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September 9, 2011

Food and Drug Administration
Center for Food Safety & Applied Nutrition
Office of Food Additive Safety (HFS-255)
5100 Paint Branch Parkway
College Park, MD 20740-3835

Attention: Dr. Mary D. Ditto

Re: GRAS Notification – Erythritol

Dear Dr. Ditto:

On behalf of Hong Kong-based O'Laughlin (Tianjin) Biotechnology Company, we are submitting for FDA review a GRAS notification for erythritol. The attached documentation contains the specific information that addresses the safe human food uses for the subject notified substance as discussed in the GRAS guidance document.

If additional information or clarification is needed as you and your colleagues proceed with the review, please feel free to contact me via telephone or email.

We look forward to your feedback.

Sincerely,

(b) (6)

Robert S. McQuate, Ph.D.
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Enclosure: GRAS Notification for O'Laughlin (Tianjin) Biotechnology Company Erythritol (in triplicate)

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GRAS ASSOCIATES, LLC

GRAS ASSESSMENT

of

Erythritol

Food Usage Conditions for General Recognition of Safety

for

O'Laughlin (Tianjin) Biotechnology Company
Hong Kong

Evaluation By

Richard C. Kraska, Ph.D., DABT
Robert S. McQuate, Ph.D.
Robert W. Kapp, Jr., Ph.D., Fellow ATS

September 9, 2011

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I. GRAS EXEMPTION CLAIM

A. Claim of Exemption From the Requirement for Premarket Approval Pursuant to Proposed 21 CFR 170.36(c)(1)[1]

O'Laughlin (Tianjin) Biotechnology Company ("O'Laughlin") has determined that its erythritol product, which meets the specifications described in Section III.E.2, is Generally Recognized As Safe (GRAS) in accordance with Section 201(s) of the Federal Food, Drug, and Cosmetic Act. This determination was made in concert with an appropriately convened panel of experts who are qualified by scientific training and experience. The GRAS determination is based on scientific procedures as described in the following sections. The evaluation accurately reflects the conditions of the intended uses of this ingredient in foods.

Signed:

(b) (6)

September 9, 2011

Robert S. McQuate, Ph.D.
GRAS Associates, LLC
20482 Jacklight Lane
Bend, OR 97702-3074

Date

B. Name & Address of Notifier

O'Laughlin (Tianjin) Biotechnology Company
Suite 1704, Chinachem Tower
No. 34-37 Connaught Road, Central,
Hong Kong

As the notifier, O'Laughlin accepts responsibility for the GRAS determination that has been made for erythritol as described in the subject notification. Consequently, the erythritol preparations meeting the conditions described herein are exempt from premarket approval requirements for erythritol.

[1] See 62 FR 18938 (17 April 1997) at: http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/ucm083058.htm.

C. Common Name & Identity of the Notified Substance

The common name of the notified substance is erythritol.

D. Conditions of Intended Use in Food

Erythritol is intended to be added for a variety of technical effects into various food categories that are described in Section IV.A. The serving levels reflect good manufacturing practices principles in that the quantities added to foods should not exceed the amounts reasonably required to accomplish its intended technical effect.

E. Basis for GRAS Determination

Pursuant to 21 CFR 170.30, O'Laughlin's erythritol preparation has been determined to be GRAS on the basis of scientific procedures as discussed in the detailed description provided below. A comprehensive literature search conducted through September 1, 2011 was used in the preparation of this safety evaluation.

F. Availability of Information

The data and information that serve as the basis for this GRAS notification will be sent to the US Food and Drug Administration (FDA) upon request or will be available for review and copying at reasonable times at the offices of GRAS Associates, LLC, located at 20482 Jacklight Lane, Bend, OR 97702-3074.

II. INTRODUCTION

A. Objective

At the request of O'Laughlin, GRAS Associates, LLC ("GA") has undertaken an independent safety evaluation of O'Laughlin's erythritol for use in foods. The purpose of the evaluation is to ascertain whether or not the intended food uses of erythritol can be considered to be generally recognized as safe (GRAS) when used as an ingredient in various food products.

B. Foreword

O'Laughlin provided GA with background information needed to enable the GRAS assessment to be undertaken. In particular, the information that was provided addressed the intended food uses, specifications for the manufactured material, manufacturing information, and unpublished toxicology studies on erythritol. Determining how much erythritol can be safely consumed, i.e., the use levels leading to dietary exposure estimates, is critical in the determination of safe exposure levels for erythritol when consumed as a food ingredient. The composite safety/toxicity studies in concert with exposure information are the two critical information components that form the basis of the GRAS evaluation.

The safety/toxicity studies, consumption/exposure information, and other related documentation were augmented with an independent search of the scientific and regulatory literature conducted through September 1, 2011. Based upon the composite information, a GRAS assessment based primarily on available safety information with corroborative information provided from common occurrence in food was undertaken. Those references that were deemed pertinent to the objective at hand are listed in Section VIII.

C. FDA Regulatory Framework

Ingredients for use in foods must undergo premarket approval by FDA as food additives or, alternatively, the ingredients to be incorporated into foods must be determined to be generally recognized as safe (GRAS). The authority to make GRAS determinations is not restricted to FDA. In fact, GRAS determinations may be provided by experts who are qualified by scientific training and experience to evaluate the safety of food and food ingredients under the intended conditions of use.

In 1997, FDA altered the GRAS determination process by eliminating the formal GRAS petitioning process and replacing the petitioning process with a notification procedure. While outlining the necessary content to be considered in making a GRAS determination, FDA encouraged that such determinations be provided to FDA in the form of a notification. However, notifying FDA of such determinations is strictly voluntary.

D. Regulatory History of Erythritol

The FDA has recognized erythritol as GRAS in response to two previous notifications. Cerestar Holding, B.V. submitted GRAS notification 76 (GRN 76; FDA, 2001a) on April 30, 2001 for erythritol isolated from *Moniliella pollinis* following fermentation. The notifier claimed the use of erythritol as a flavor enhancer, formulation aid, humectant, nutritive sweetener, stabilizer and thickener, sequestrant, and texturizer in foods. The food categories and levels of use claimed in GRN 76 are identical to those of this notification. The FDA issued a "no questions" letter regarding the GRAS status of erythritol under the intended conditions of use on September 11, 2001 (FDA, 2001b). The Mitsubishi-Kagaku Foods Corporation of Tokyo, Japan submitted a GRAS Notification (GRN 208; FDA, 2006) on July 7, 2006 for erythritol isolated through fermentation of *Trichosporomoides megachiliensis*. The conditions of use were identical to those in GRN 76. The purpose of the submission was to assert that production of erythritol using a different microorganism was GRAS. On November 20, 2007, the FDA issued a corrected letter[2] stating "the agency has no questions at this time" regarding the notifier's conclusion that erythritol is GRAS (FDA, 2007).

In addition to the GRAS notifications identified above, the Joint Expert Committee on Food Additives (JECFA) issued a report on erythritol in 2000, the European Commission issued an Opinion of the Scientific Committee on Food on Erythritol in 2003 (European Commission, 2003), and the European Food Safety Authority issued Scientific Opinions on the safety of erythritol in 2010 (EFSA, 2010). The JECFA report (WHO, 2000b) comprises an extensive 56-page review of the biology, ADME, and toxicology of erythritol. The report concludes:

> The NOELs for physiological responses to orally administered erythritol in animals were mostly between 1 and 2 g/kg bw per day. Since the observed effects of erythritol in animals are a physiological response to an osmotically active substance, application of a safety factor to the NOELs observed in studies in experimental animals was considered inappropriate. In humans, a dose of 1 g/kg bw per day consumed in a variety of foods for five days was without effect, although the same and lower doses consumed in aqueous solution as a bolus dose after fasting resulted in laxation. The Committee established an ADI 'not specified'[3] for erythritol for use as a sweetening agent.

In the 2003 EFSA report, the EU Scientific Committee on Food concluded that erythritol is safe for use in foods. The report stated that the use of erythritol as a food additive is acceptable, and a numerical ADI was not needed. However, this approval did not cover its use in beverages because the opinion stated that the laxative threshold may be reached, especially by young consumers.

[2] The original FDA letter expressing no objection was dated January 25, 2007.

[3] There are occasions when JECFA considers the use of an ADI in numerical terms not to be appropriate. This situation arises when the estimated consumption of the additive is expected to be well below any numerical value that would ordinarily be assigned to it. Under such circumstances, JECFA uses the term "ADI not specified". The Committee defines this term to mean that, on the basis of available data (chemical, biochemical, toxicological, and other), the total daily intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food, does not, in the opinion of the Committee, represent a hazard to health (WHO, 1987).

In 2010, EFSA issued a scientific opinion following a pediatric study on the gastrointestinal tolerability of erythritol (EFSA, 2010). Erythritol intake resulting from an incorporation rate of 2.5% in beverages (i.e., 0.59 g/kg bw/day) is below the NOAEL for laxative effects (i.e., 0.71 g/kg bw/day). However, the EFSA Panel noted "that the margin of safety (MOS) between this NOAEL and the estimated daily intake of erythritol resulting from an incorporation rate of 2.5% in beverages is 1.24. The EFSA Panel concluded that, particularly when the other food categories of use are taken into consideration, "there is a safety concern with respect to GI tolerability for the use of erythritol in beverages at a maximum use level of 2.5% for non-sweetening purposes." In addition, as with all sweeteners, levels of use are self-limiting due to organoleptic factors and consumer taste preferences.

III. INGREDIENT IDENTITY, CHEMICAL CHARACTERIZATION, MANUFACTURING PROCESS & PURITY

A. Common or Usual Name & Identity of Notified Substance

Erythritol is the common or usual name of the product that is the subject of the GRAS evaluation, and the specific substance that is the subject of this safety evaluation is identified as erythritol as produced and sold by O'Laughlin. The compositional features of the subject ingredient are described in more detail elsewhere in this Section. The Chemical Abstract Service (CAS) registry number for erythritol is 149-32-6.

B. Chemical Name

Erythritol is a 4-carbon polyol which is also known as 1,2,3,4-butanetetrol, *meso*-erythritol, erythrol, erythrite, paycite, antierythrite, and phycitol (ChemIDPlus, 2010).

C. Chemical Identity of Erythritol

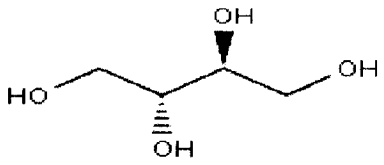
Erythritol has a molecular formula of $C_4H_{10}O_4$ and a molecular weight of 122.12 daltons. The chemical structure of erythritol is given in Figure 1. The infrared spectrum and mass spectrum, as well as measurements of various thermodynamic parameters, solubility and the organoleptic characteristics for O'Laughlin's erythritol, are presented in Appendix A. Erythritol naturally occurs in mushrooms, watermelon, pears, grapes, soy sauce, wine, sake, and beer at levels up to 0.13%. It is a four-carbon sugar alcohol which is heat stable, non-hygroscopic, and exists as a white, odorless crystal. A summary of the physical and chemical properties of erythritol is presented in Table 1.

D. Manufacturing Process

Erythritol is produced by the pure culture fermentation using a non-pathogenic and non-toxigenic microbial fermentation. The organism is identified as non-GMO *Moniliella pollinis* which utilize a carbohydrate-based medium under certain conditions to produce erythritol (see Appendices B-1 and B-2). Once the fermentation process is complete, the microorganisms are killed by heating. The heat-sterilized broth is filtered, followed by ion-exchange resin purification, and then treated with activated charcoal after which it undergoes concentration and ultrafiltration. It is subsequently crystallized, washed and dried to yield pure erythritol.

Fermentation: The starting material in the production of erythritol is a simple sugar-rich substrate which is fermented by yeast-like fungus *Moniliella pollinis*. The sterile medium contains dextrose, diammonium phosphate, magnesium sulfate, yeast spore clump stems and yeast extract. This medium is used for seed culture and for production culture. For these cultures the strain inoculum preparation is transferred under aseptic conditions into the medium. In order to achieve

Figure 1. Chemical Structure of Erythritol[a]



[a] ChemIDplus, 2010.

Table 1. Physical & Chemical Properties of Erythritol[a]

GENERIC NAME	ERYTHRITOL
Formal (IUPAC) name	1,2,3,4-butanetetrol
CAS Registry No.	149-32-6
Molecular formula	$C_4H_{10}O_4$
Molecular weight	122.12 daltons
Melting Point	118-120°C
Boiling Point	329-331°C
Solubility in water	Soluble
Solubility in ethanol	Slight
Solubility in DMSO	Insoluble
Color	White
Odor	Odorless
Taste	Sweet
Form	Crystal

[a] European Commission, 2003; Chemical Book, 2011.

inoculum preparation is transferred under aseptic conditions into the medium. In order to achieve maximum yield, the fermentation temperature is maintained within a specified range. When the dextrose is completely consumed, the fermentation broth is heated to 85-90°C to completely inactivate the microorganisms.

Purification: Following complete inactivation of *Moniliella pollinis* by heat treatment, the dead cells from the fermented broth are separated by filtration. The supernatant is subjected to a decolorization process that is carried out twice utilizing fresh activated charcoal each time. Upon completion of the second activated charcoal decolorization step, the supernatant is exposed to ion exchange resin to remove inorganic salts, pigments and organic impurities. (Certification of the membranes used can be found in Appendix B-3). After vacuum evaporation, the purified fermentation broth is subjected to cooling crystallization followed by filtration. The liquid is concentrated by vacuum evaporation and subjected to a crystallization procedure by using water. This is followed by filtration. The mother liquor obtained following crystallization is treated with hydrochloric acid and sodium hydroxide, which is subsequently recycled for use in the evaporation and crystallization steps. The crystals obtained above are dissolved in hot water and subjected to decolorization using charcoal. The filtrate is further purified using a second crystallization step. The crystals are separated by centrifugation, followed by washing with water, evaporation, drying in hot air steam, sifting and packaging. The final product is $\geq$ 99.5% pure erythritol. The production process for erythritol is monitored at multiple points. A summary of the quality control performed by O'Laughlin during the production process is presented in Table 2.

Table 2. Quality Control of Manufacturing Process for Erythritol

ITEM	QUALITY CONTROL POINT
Fermentation process	Content: 120g/L; Purity Dx[a]: not less than 85%
Ion exchange process	Conductivity: not more than 100 us/cm²
Evaporation process	Bx[b]: not less than 70%
Crystallization process	Yield coefficient: not less than 50%
Drying process	Water content: not more than 0.2%

[a] Net erythritol content, expressed as a percentage.
[b] Brix molasses, refers to the sugar syrup in the Baume mass fraction, expressed as a percentage.

As indicated, the erythritol is produced by a dextrose fermentation using the yeast *Moniliella pollinis*. The identity of the microorganism, *Moniliella pollinis*, is confirmed by biophysical and biochemical classification, 26S rDNA phylogenetic analysis. This organism is both non-toxicogenic and non-pathogenic. Although the erythritol produced by the notifier in GRN 208 is isolated from *T. megachiliensis*, an evaluation of the toxicity for both *M. pollinis* and *T. megachiliensis* was provided. The summary in GRN 208 stated:

> Both *M. pollinis* and *T. megachiliensis* are osmophilic fungi and together with related species can contaminate high sugar foods such as syrups, jams and honey. Some *Moniliella* species are found in low pH foods (pickles, sauces) and both *Moniliella* spp. and *Trichosporonoides* spp. have been isolated from foods high in fat (e.g. margarine, ghee) (Samson & van Reenen-Hoekstra 1988).

Both fungi are able to grow at 35-37°C. A search of the literature, major fungus culture collection and taxonomic databases failed to reveal any documented evidence of *M. pollinis* or *T. megachiliensis* being pathogenic to humans. Related species have been isolated from clinical material although they appear to be rare occurrences (Kockova-Kratochvilova et al. 1987; McKenzie et al. 1984).

There is no indication in the literature that *T. megachiliensis* or *M. pollinis* produce toxic metabolites or antimicrobial compounds. However, both fungi have been reported to produce pigmented metabolites in culture (Dooms et al., 1971; Inglis & Sigler 1992) although the petitioners have provided information indicating that color changes in the fermentation broth are minor and can be explained by variation in broth components and the effect of heat treatment.

The ingredients used for the culture medium of *Moniliella pollinis* are food grade and are commonly used in the food industry for such purposes. The erythritol production as well as the components dextrose, hydrochloric acid, sodium hydroxide, diammonium phosphate, magnesium sulfate and yeast extract used in the mother liquor treatment process that is recycled comply with Food Chemicals Codex 7th Edition specifications (See Appendices B-4, B-5, B-6, B-7, B-8, B-9 and B-10, respectively). The polyethersulfone resin used in the production process complies with 21 CFR 177.2440. The erythritol is prepared in accordance with current Good Manufacturing Practices of Codex Alimentarius General Principles of Food Hygiene at the O'Laughlin facilities in Hong Kong as certified by the SGS-CSTC Standard Technical Services Co. Ltd. Beijing, China (See Appendix B-11).

A detailed description and summary flow chart for the manufacturing process of erythritol by O'Laughlin are located in Appendix C.

E. Product Purity

1. Identification of Erythritol

Erythritol has well-known characteristics which can be utilized for its identification. Erythritol is known to be stable under heat, acid, and alkaline conditions. Erythritol has a melting point of 119-123°C and a boiling point of 329-331°C. Erythritol is water soluble and is slightly soluble in alcohol. The general properties of O'Laughlin's erythritol are presented in Appendix A. This includes mass spectra and infrared spectra for erythritol, thermodynamic data and comparisons to other known sweeteners.

2. Specifications of Erythritol

O'Laughlin has established specifications for the typical composition and the maximum microbiological, heavy metal and pesticide contaminant levels of erythritol which are intended to maintain the food grade status of the final product. The standard methods that are utilized in analyzing the O'Laughlin's erythritol are described in Appendix D. A summary of the critical

specifications for erythritol can be found in Table 3. To demonstrate conformance with the food-grade specifications in Table 3, O'Laughlin analyzed five lots of its high purity erythritol (see Appendix E-1). The certificates of analysis of these lots can be found in Appendix E-2. All five lots of erythritol were within the food-grade specifications established for erythritol, indicating that the production process is capable of consistently producing food-grade product. Pesticide analyses for a single batch of O'Laughlin's erythritol are provided in Appendix F. The collection of these reports demonstrates that O'Laughlin's erythritol is well characterized and meets the necessary purity criteria.

Table 3. Specifications for Erythritol as Manufactured by O'Laughlin

COMPONENT	SPECIFICATION
Erythritol (anhydrous basis)	99.5-100.5%
Reducing Sugars	≤0.3%
Ribitol and Glycerol	≤0.1%
Lead	≤0.5 ppm
Total Aerobic plate count	≤300 (cfu/g)
Total Aerobic Yeast Count	≤50 (cfu/g)
Total Aerobic Mold	≤50 (cfu/g)
Coliform (MPN/100g)	Negative
E. coli (MPN/100g)	Negative
Foreign matter, Contaminants	Absent

3. Organism Residue

Both microorganisms, *Trichosporonoides megachiliensis* and *Moniliella pollinis,* have been reviewed for safety and were found to be acceptable by JECFA (1999), the SCF (SCF, 2003), and the Committee on Food Chemicals Codex . Both are osmophilic fungi and together with related species can contaminate high sugar foods such as syrups, jams and honey. Some *Moniliella* species are found in low pH foods (pickles, sauces), and both fungi have been isolated from foods high in fat (Samson & van Reenen-Hoekstra 1988). There is no indication in the literature that either *T. megachiliensis* or *M. pollinis* produce toxic metabolites or antimicrobial compounds. There was also no indication found in the literature indicating any microbiological contamination problems associated with erythritol. Further, the water content of the erythritol product (<0.2%) is below the level that would support microbial growth. The fermentation broth containing erythritol is separated from the organisms and is subjected to purification treatment similar to those for the carbohydrate sweeteners and sugar alcohols, e.g., ion-exchange resin, activated charcoal, and crystallization. The final product is a material containing not less than 99.5% erythritol. The fermentation broth produced by both fungi has been tested for toxicogenic activity. The safety of *Trichosporonoides megachiliensis* was shown in an acute oral toxicity study in which an erythritol fermentation broth was administered to rats (Kashima Laboratories, 1995), No deaths or toxic effects attributable to the fermentation broth were observed. A minimum lethal dosage of the fermentation broth in rats therefore exceeds the 5000 mg/kg bw dose in this study. A 4-week repeated-dose oral toxicity study of *M. pollinis* fermentation broth in rats demonstrated that dietary levels up to 2.5% (the highest dose tested) corresponding to an overall intake of 2.1 g/kg bw/day did not induce any treatment related changes (Lina, 2002;

European Commission (2003). The O'Laughlin erythritol product will not expose consumers to the producing organisms because they are destroyed by heat treatment of the fermentation broth and are subsequently removed by filtration and purification.

4. Stability Data

Erythritol, as produced by O'Laughlin, is acid stable when heated up to 150°C for 1 hour which is described in Appendix G. Appendix G also shows the effect of humidity on the moisture content of erythritol.

For storage of erythritol, O'Laughlin recommends the conditions detailed in Table 4.

Table 4. Recommended Storage for O'Laughlin Erythritol

STORAGE CONDITIONS	AMBIENT (10-32°C) KEEP FROM SUNLIGHT; STORE IN ODOR-FREE ENVIRONMENT; LOW HUMIDITY CONDITIONS RECOMMENDED TO MINIMIZE CAKING/DEGRADATION POTENTIALS
SHELF LIFE	36 MONTHS

IV. INTENDED FOOD USES & DIETARY EXPOSURE

A. Intended Uses

Customers of O'Laughlin intend to use erythritol in a limited number of human food categories where the high purity erythritol could function to achieve various functional effects. Erythritol is intended for use in the same foods and at levels of addition as designated by Mitsubishi-Kagaku Foods Corporation for erythritol in GRN 208 (FDA, 2006) and as notified previously by Cerestar Holding, B.V. in GRN 76 (FDA, 2001a). The proposed food uses of the erythritol include: flavor enhancer,[4] formulation aid,[5] humectants,[6] nutritive sweetener,[7] stabilizer and thickener,[8] sequestrant,[9] and texturizer.[10] The intended food use categories and use levels of erythritol are presented in Table 5.

Table 5. O'Laughlin's Intended Conditions of Use

FOOD CATEGORY	LEVEL OF USE
Reduced and low-calorie and non-carbonated beverages; Dairy drinks (chocolate and flavored milks)	3.5%
Frozen dairy desserts (regular ice cream, soft serve, sorbet); Puddings (instant, phosphate set); Yogurt (regular and frozen)	10%
Bakery fillings (fruit, custard, cream, pudding); Cakes and cookies (regular and dietetic)	15%
Fat-based cream used in modified fat/calorie cookies cakes, and pastries; Chewing gum; Soft candies (non-chocolate, plain chocolate, chocolate coated)	60%
Hard candies (including pressed candies, mints, and cough drops)	99%
Sugar substitutes (carrier)	100%

B. Dietary Exposure

Erythritol is naturally occurring, at levels up to 0.13%, in a number of common foods which are part of the American diet. These foods include fruit, such as pears, melons, and grapes, as well as mushrooms, and fermented foods including soy sauce, wine, and cheese. Intake of naturally-occurring erythritol varies with diet between countries. An estimated intake of naturally occurring

[4] As defined in 170.3 (n)(11).
[5] As defined in 170.3 (n)(14).
[6] As defined in 170.3 (n)(16).
[7] As defined in 170.3 (n)(21).
[8] As defined in 170.3 (n)(28).
[9] As defined in 170.3 (n)(26).
[10] As defined in 170.3 (n)(32).

erythritol in the US is 24 mg/day, in Japan is 105 mg/day. An amount of 47 mg/day is a Danish estimate (DVFA, 2001).

Erythritol produced by O'Laughlin using *Moniliella pollinis* will be used under the same conditions of use as described in GRN 76 and GRN 208. Therefore, erythritol produced by O'Laughlin will have the identical estimated exposure calculations as presented in GRN 76 and GRN 208. The Cerestar Expert Panel maintained the mean and 90th percentile EDIs (estimated daily intakes) for erythritol would not be expected to exceed 4.9 and 11.9 g/day, respectively, however, the agency produced its own EDI calculations for erythritol under the above conditions of use as 13 g/person/day at the mean and 30 g/person/day at the 90th percentile (FDA, 2007).

V. REVIEW OF SAFETY DATA ON ERYTHRITOL

A. Common Knowledge Regarding Safe Erythritol Consumption

Erythritol has been used as a food ingredient around the world for decades. As a result, a number of comprehensive reviews of the safety of erythritol have been published (Bernt et al., 1996 & 2000; Munro et al., 1998; JECFA (WHO 2000a, b); EFSA, 2010; GRN 76 (FDA, 2001a) and GRN 208 (FDA, 2006). The JECFA and EFSA reviews have found erythritol to be safe for human consumption with an ADI "not specified." The Expert Panel for GRN 76 estimated that consumption of 40 g/person/day would be safe. The only health issues noted are a laxative effect, which in all studies is related to intake of erythritol as a large bolus resulting in a physiological response of the body to the substantial intake of an osmotically active substance. The most recent review was an analysis of erythritol toxicity published by EFSA in 2010.[11] Since extensive reviews are readily available,[12] the following summary contains highlights of the previously published safety studies.

B. Safety Data on Erythritol

1. Absorption, Distribution, Metabolism & Excretion (ADME) Studies

Erythritol is well-known as a non-caloric sweetener which is almost completely absorbed after consumption, is not metabolized, and then is excreted unchanged in the urine. Erythritol is 60-70% as sweet as sugar, yet it does not affect blood sugar or insulin levels (Noda et al, 1994), nor does it cause tooth decay (Kawanabe, 1992). Studies have shown that about 90% of ingested erythritol is absorbed from the small intestine and excreted in urine (Noda et al, 1988, 1994; Ishikawa et al., 1992). Thus, less than 10% of ingested erythritol is fermented by the intestinal microflora into short-chain fatty acids (Noda and Oku, 1992; Bornet et al., 1996a, b). Since erythritol is almost completely absorbed in the small intestine, gastric side effects from excessive consumption such as a laxative effect, flatulence, and abdominal pain are greatly reduced in comparison to other sugar alcohols. Only when consumed in extremely large quantities, such that consumption occurs faster than absorption, will it cause laxative effects. The laxative effects in humans are thought to occur around 0.5 g/kg bw/day for a single dose (Umecki, 1992).

ADME studies of erythritol have been performed in mice, rats, dogs, and humans. In all species, excretion of erythritol ranged from 60-90%, depending on the dose (Bornet et al. 1996a, b; Dean et al., 1996; Hiele et al., 1993; Ishikawa et al., 1996; Lina et al., 1996; Nakayama, 1990a, b; Noda, 1994; Noda et al., 1988; Noda et al., 1996; Noda & Oku, 1992; Tetzlof et al., 1996 Til et al., 1996; van Ommen et al., 1996). In one representative study, Noda et al. (1994) administered a single dose of 0.3 g/kg bw to 5 men after a 12-h fast. The plasma concentration of erythritol peaked at 430 g/mL 30 min after treatment, with a $t_{1/2}$ of 3.4 h. Approximately 90% of the administered dose (90.3 ± 4.5%) was recovered unchanged in the urine within 48 h. The urinary excretion rate of erythritol was 11.6%/h for the period of 0-3 h, and decreased to 0.2%/h for the

[11] The EFSA report is available online at http://www.efsa.europa.eu/en/efsajournal/doc/1650.pdf.
[12] The Comprehensive WHO report is available at http://apps.who.int/ipsc/database/evaluations/chemical.aspx?chemID=961.

period of 24-48 h. Utilizing the factorial method for determining the energy value of fermentable non-digested carbohydrates (Livesay, 1992), the caloric value of erythritol is estimated to be 0-0.2 kcal/g in humans given oral doses lower than 25 g/day or 0.34 g/kg bw (SCF, 2003).

2. Acute Studies

Single-dose toxicity studies of erythritol date back to the 1930s. Beck et al. (1936, 1938) administered single-doses of erythritol to mice, rats, and dogs. Erythritol was found to be essentially non-toxic, with a LD_{50} > 5 g/kg bw. Table 6 contains a summary of these data.

Table 6. Studies of Acute Toxicity of Erythritol[a]

Species	Sex	Route	LD_{50} (mg/kg bw)	Reference
Mouse	NR	Intraperitoneal	7000-9000	Beck et al. (1936)
Mouse	NR	Intraperitoneal	~8000-9000	Beck et al. (1938)
Rat	NR	Oral	>18000	Beck et al. (1938)
Rat	Male	Intravenous	6600	Yamamoto et al. (1987)
Rat	Female Male	Subcutaneous	9600 ≥16000	Yamamoto et al. (1987)
Rat	Female Male	Oral	>16000 13100	Yamamoto et al. (1987)
Dog	Female Male	Oral	13500 >5000	Ozeki et al. (1988)

[a] Reproduced from WHO, 2000b.

3. Subchronic Toxicity Studies

Short term toxicity studies have been published for mice, rats, and dogs. The same general effects observed in all species due to erythritol were increased water intake, diuresis, increased urinary volume, and increased kidney weight. All of these effects were considered an adaptive response to the diuretic effect of erythritol, as opposed to toxic effects. The NOAELs for dietary administration of erythritol was 5% of the diet for all species, equivalent to 7.5 g/kg bw/day in mice, 2.5g g/kg bw/day in rats, and 1.7 g/kg bw/day in dogs. When administered by gavage, the NOELs were 2 g/kg bw/day for rats and 1.2 g/kg bw/day for dogs. A summary of available short term toxicity studies with erythritol can be found in Table 7.

Table 7. Subchronic Toxicity Studies with Erythritol

Species	Route	Dose (g/kg bw/day)	Time	Significant Effects Observed	LOEL / NOEL (g/kg bw)	Reference
Mouse	Oral-diet		13 weeks	**Increased**: water intake, urine volume, urinary protein & marker enzymes, kidney weight, cecal weight	NOEL: 7.5	Til et al., 1992,1996
Rat	Oral-diet	0, 5, 10	28 days	**Increased**: urine volume, transient diarrhea, water intake, cecal weight **Decreased**: serum triglyceride	LOEL: 5	Oku & Noda, 1990
Rat	Oral-diet	Males: 5.4, 11 Females: 5, 9.9	28 days	**Increased**: kidney weight, cecal & spleen weight, alkaline phosphatase activity	LOEL: 5	Til & Wijands, 1991 Til & Modderman, 1996
Rat	Oral-gavage	Females:8	28 days	**Increased:** diarrhea, water intake, kidney weight **Decreased**: food consumption, osmotic pressure, serum Na, Cl	N.D.	Shibata et al., 1991
Rat		Male: 0, 1.1, 2.9	28 days	**Increased:** water intake, erythrocyte, leukocyte, platelet counts,	NOEL: 1	Kanai et al., 1992
Rat	Oral-gavage	0, 1, 2 ,4, 8	13 weeks	**Increased**: water intake, diarrhea, urinary volume, urinary Na, K, & Cl; blood urea nitrogen, sinusoid dilatation adrenal glands, kidney & adrenal weight, dilatation renal tubules **Decreased**: plasma Na, Cl, spontaneous movement	NOEL: 2	Yamamoto et al., 1989
Rat	Oral-diet	0, 2.5, 5, 10	13 weeks	**Increased**: cecum weight, kidney weight, urine volume, water intake, urine NAG, serum alkaline phosphatase	NOEL: 2.5	Til et al. 1991, 1996
Rat	Intra-venous	0, 1, 1.73, 3	180 days	**Increased**: water intake, urine volume, reticulocyte count, adrenal and kidney weight, serum K, blood urea nitrogen **Decreased**: body weight, serum K	NOEL: 1	Kamata, 1990a
Dog	Oral-gavage	0, 1.25, 2.5, 5	13 weeks	**Increased**: water intake, urine volume, diarrhea, vomiting, thymic atrophy, histopathologic changes in kidney	NOEL: 1.25	Yamaguchi et al., 1990
Dog	Intra-venous	0, 1, 2.2, 5	180 days	**Increased**: blood urea nitrogen, vomiting, water intake, urine volume, bladder hemorrhage, urine Na, Cl, K, histopathologic changes in prostate **Decreased**: urinary Cl	LOEL: 1	Kamata, 1990b
Dog	Oral-diet	0, 0.7, 1.7, 3.8	53 weeks	**Increased:** water intake, urine volume	NOEL: 1.7	Dean & Jackson, 1992 Dean et al., 1996

In a representative study, Til et al. (1992, 1996) performed toxicity studies with mice. Mice were fed diets containing 0, 5, 10, or 20% erythritol *ad libitum* for up to 13 weeks (10 CD-1 mice/sex/group). Mice were monitored daily for clinical signs of toxicity and changes in body weight and feed consumption. No deaths occurred. No statistically significant changes in mean body weight, feed intake, or clinical biochemistry were measured. Both male and female mice showed a dose-related increase in water intake and urine volume which was significant at the 10% and 20% doses. In addition, there was a dose-related increase in the 24-h excretion of protein, GGT and NAG activities, sodium, potassium, calcium, phosphate, citrate, and creatinine concentrations in animals of each sex (significant at the 20% dose). A significant increase in kidney weight and cecum weight in both sexes occurred at the 20% dose. No macroscopic or microscopic findings consistent to either group were observed. The NOEL was determined to be 5% erythritol, equivalent to 7.5 g/kg bw/day.

4. Chronic Studies

Two studies of the effects of long term administration of erythritol to rats have been performed. In these studies, erythritol did not affect survival and did not induce carcinogenesis. The results of these studies are summarized in Table 8.

Table 8. A Summary of Chronic Studies of Erythritol Intake in Rats

Species	Route	Dose (g/kg bw/day)	Time	Significant Effects Observed	LOEL / NOEL (g/kg bw)	Reference
Rat	Oral-diet	Males: 0, 0.46,1.4,5 Females: 0, 0.54, 1.7, 7.5	78 weeks	**Increased:** soft feces, water intake, urine volume, urine Ca, plasma alkaline phosphatase, cecal weight, kidney weight **Decreased:** body weight	NOEL: 1.4	Til & van Nesselrooij, 1994
Rat	Oral-diet	Males: 0, 0.86, 2.2, 4.6 Females: 0, 1, 2.6, 5.4	104 weeks	**Increased:** urine volume, water intake, cecal weight, urinary Ca & electrolytes, kidney & adrenal weight **Decreased:** serum triglyceride	NOEL: 0.86	Lina et al., 1994, 1996

In the 78 week study (Til and van Nesselrooij, 1994) erythritol of greater than 98.5% purity was administered in the diet to groups of 20 Wistar (Crl:WI(WU)BR) rats at concentrations of 0 (control), 1, 3 or 10%. As a result of treatment, soft feces were observed in the high-dose animals during the first weeks of the study, but resolved thereafter. Behavior and appearance of the rats were unremarkable for the first year, with age-related changes noted in all groups, including controls, in the remaining 6 months of the study. A number of isolated, statistically significant, changes in hematological parameters occurred; however, they were considered to be isolated transient findings and therefore unrelated to erythritol treatment. Similarly, although a number of significant changes in blood chemistry parameters were recorded during the study, only the increases in alkaline phosphatase activity in the high-dose animals were considered to be related to treatment. The remaining changes in clinical chemistry parameters either showed

no dose response, lacked consistency across sex and time or were within the normal range of variation, and as such were not considered to be toxicologically significant. Slightly increased urinary output was attributed to the increased load on the kidneys brought about by the high renal clearance of erythritol. Increased water intake occurred in a dose-dependent fashion to compensate for this change. The increases in calcium excretion were considered to be of no toxicological significance since nephrocalcinosis was not observed, and no histopathological correlates were observed in the kidney. Since there were no histopathological effects in the large intestine attributable to treatment, the increased cecal weights was considered to represent physiological responses of no toxicological significance no significant toxicity was attributed to erythritol treatment although physiological responses, including decreased body weight gain, increased urinary volumes and cecal enlargement were observed. Even at the 10% dose level, the highest dose tested, erythritol was essentially non-toxic.

In the Lina et al. (1994, 1996) studies, groups of 50 Wistar rats were fed a diet containing 0, 2, 5 or 10% erythritol for 104 weeks(approximately 0, 0.86, 2.2 or 4.6 and 0, 1.0, 2.6 or 5.4 g/kg body weight/day for male and female rats, respectively. This includes a 3 week adaptation period where dietary concentrations were gradually increased. Animals were observed daily for toxicity. Body weight, feed and water consumption, ophthalmic observations, hematological assessments, urine and fecal assessments, and gross and histopathological examination of the organs were performed at regular time points throughout the study period. The authors report a significantly lower body weight of male rats at the intermediate and high dose, and female rats at the high dose during the majority of the study. However, no treatment-related effects on mortality or the general condition or behavior of the animals was observed. Both males and female rats in the 5 and 10% groups had a significant increase in water consumption when compared to controls. In addition, rats at the 10% level had statistically significant increases in urine volume at all times except 102 weeks. The osmolarity of the urine was significantly decreased in males on the 10% diet, and urinary excretion of GGT, NAP, sodium, potassium, phosphate, total and low-molecular-mass protein, calcium, and citrate was increased in males with the 10% diet. No treatment-related effects were noted on hematological and clinical biochemical parameters measured. Cecal weight was increased in male rats at 52, 78, and 104 weeks and female rats at 104 weeks in the 10% group. No histopathological change was associated with this increase. The absolute and relative weights of the adrenals in females at 104 weeks with the 10% diet were increased. No pheochromocytomas or histopathological change were associated with this increased weight. An increase in kidney weights (absolute and relative) was observed in male rats fed 10% diet at 52 and 78 weeks, but not at terminal sacrifice. A non-significant increase in kidney weight was also observed in female rats at the 5% and 10% level. An increase in pelvic nephrocalcinosis was observed in all treated female rats, but not in male rats. This was not considered toxicologically significant since it is a common age-associated lesion in female rats and the incidence in the control groups was considered low. In a separate study of rats in the same lab, the incidence of nephrocalcinosis was comparable to that in the treated females in this study. Erythritol was not carcinogenic at doses up to 10% of the diet. The NOEL was 2% of the diet based on increased water intake, cecal weights, and urine volume.

5. Reproductive/Developmental Studies

Reproductive and developmental toxicity studies have been performed in mice, rats, and rabbits. "No reproductive or developmental toxicity was observed at doses up to 8 g/kg bw/day in mice treated by gavage or at doses representing up to 10% of the diet of rats (WHO, 2000b)." Even at high doses, erythritol has no adverse effects on fertility or on the developing fetus. These studies are summarized in Table 9.

Table 9. A Summary of Reproductive & Developmental Studies with Erythritol

Species	Route	Dose (g/kg bw/day)	Time	Significant Effects Observed	Reference
Mice	Oral-gavage	0, 1, 2, 4, 8	Age 6 weeks – day 6 gestation	**Increased**: diarrhea No effect on reproductive performance	Tateishi et al., 1989
Mice	Intrave-nous	0, 1, 1.73, 3	Age 6 weeks – day 6 gestation	**Increased**: water intake, death(low incidence),renal tubule dilatation No effect on reproductive performance	Tateishi et al., 1992
Rat	Oral-diet	Males: 0, 1.5, 3.1 ,6.5 Females: 0, 1.7, 3.3, 7.1	Pre-mating through lactation for 2 consecutive generations	**Increased**: diarrhea (F_0), No effect on reproductive performance or fertility of F_0 or F_1 **Decreased**: body weight of F_1 pups **NOEL for reproductive toxicity**: 3.1g/kg bw/day	Smits-van Prooije et al., 1996a, Waalkens-Berendsen et al., 1996
Mice	Intrave-nous	0, 1, 2, 4	Days 6-15 gestation	**Increased:** Cleft palate, wavy ribs, fused sternebrae in pups at 4 g/kg bw dose No effect on reproductive performance or development of offspring **Decreased:** spontaneous movement, feed consumption at 4g/kg bw dose **NOEL for maternal & developmental toxicity:** 2 g/kg bw/day	Ota et al., 1990
Rats	Oral-diet	0, 1.7, 3.3, 6.6	Days 0-21 gestation	**Decreased:** body weight, weight gain in dams Not embryotoxic, fetotoxic, or teratogenic **NOEL for maternal toxicity:** 5% diet (3.3 g/kg bw/day)	Smits-van Prooije et al., 1996b)
Rabbits	Intrave-nous	0,1,2.2,5	Days 6-18 gestation	**Increased:** water intake,, skeletal variations at high dose (not significant) **Decreased:** feed consumption, body weight of fetuses at high dose (not significant) **NOEL for maternal toxicity: 2.2 g/kg bw/day**	Hashima Laboratory, 1989, Shimizu et al., 1996

6. Genotoxicity/Mutagenicity Studies

Genotoxicity and mutagenicity studies of erythritol have shown that erythritol is not mutagenic or clastogenic *in vitro*. A summary of these studies is located in Table 10.

Table 10. Results of Assays for the Genotoxicity of Erythritol[a]

End-point	Test System	Concentration	Results	Reference
Reverse Mutation[b]	S. typhimurium TA98,TA100,TA1535, TA1537, TA1538	370-30,000 ug/plate	Negative	Blijleven, 1990
Reverse mutation[c]	S.typhimurium TA98, TA100, TA1537; E. coli WP2 uvrA	15.8-5000 ug/plate	Negative	Kawamura et al., 1996
Chromosomal aberration[c]	Chinese hamster fibroblast line CHL/IU	1.25-10 mmol/L	Negative	Nakatsuru et al., 1988 Kawamura, et al., 1996

[a] Reproduced from JEFCA, 2000.
[b] In the presence and absence of a metabolic activation system from the 900 X g fraction of the livers of Aroclor 1254-induced male rats.
[c] *In the presence and absence of a metabolic activation system of unspecified origin.*

C. Clinical Studies with Erythritol

Human studies of erythritol have focused on single-dose and repeat-dose studies to determine the NOEL for gastrointestinal symptoms, allergenicity, and the energy value of erythritol (described in section V.B). Other than a very rare occurrence of allergic reaction and the known gastrointestinal symptoms associated with ingestion of polyols, no adverse effects related to erythritol consumption have been reported.

1. Single-Dose Studies

A number of single-dose studies have examined the laxative effect of erythritol and compared it to sucrose and sorbitol. A summary of these studies is located in Table 11. Overall, Umeki (1992) reported no diarrhea in healthy volunteers given a 0.46 g/kg bw dose, Takahashi (1992a,b) found no laxative effect at 0.47g/kg bw (males), and in a separate study at 0.57 g/kg bw (in females). The minimum dose resulting in diarrhea in all these studies ranged from 0.6-0.7 g/kg bw. Oku and Okazaki (1996a, b) report no laxative effect below 0.7 g/kg bw. Female subjects seemed to show a greater tolerance to laxative effects than males. In all of these studies, sucrose had no laxative effect, while sorbitol caused laxation at significantly lower doses than erythritol (ranging

from 0.15-0.25 g/kg bw). Overall, the results indicate that the NOEL for gastrointestinal symptoms is between 0.5-1.0 g/kg bw.

Table 11. Studies of Effect of a Single Dose of Erythritol in Healthy Volunteers

SUBJECTS	DOSE	RESULTS	NOEL (G/KG BW)	REFERENCE
6 men, age 26-46	0.46, 0.62, 0.77, 0.92 g/kg bw	Diarrhea	0.46	Umeki, 1992
8 men, 4 women	Men: 0.47, 0.62, 0.78 g/kg bw, Women: 0.57, 0.76, 0.94 g/kg bw	4 men, 1 woman dropped out Diarrhea	0.47	Takahashi, 1992a
5 men, Ages 45-58	0.3 g/kg bw	No effects on glucose, insulin, cholesterol, triglycerides, fatty acids or electrolytes	NR	Noda et al., 1994
3 men, 3 women, Ages 24-43	1 g/kg bw	**Increased**: Diarrhea, cramping, stomach discomfort, flatulence No effect on plasma glucose or insulin	<1	Bornet et al., 1996a
12 men, 12 women, ages 20-46	0.4, 0.8 g/kg bw	No adverse GI effects; no changes in osmolarity, electrolytes, insulin or glucose levels	NR	Bornet et al., 1996b
5 NIDDM patients, average age 52 ± 19 yrs	20g/person (body weight NR)	No effects on carbohydrate metabolism	N/A	Ishikawa et al., 1996
7 men, 12 women	Men: 25, 50,75g Women: 25, 37.5, 62.5g	**Increased**: nausea, borborygmus, thirst, flatulence	Men: 0.66 Women: 0.80	Oku & Okazaki, 1996a,b
64 young adults	20, 35, 50g	**Increased**: borborygmus & nausea at 50g dose	0.78	Storey et al., 2007

2. Repeated-Dose Studies

Single-dose studies, such as Bornet et al. (1996a) described above, demonstrate that ingestion of a bolus of erythritol at 1 g/kg bw induces gastrointestinal symptoms, such as diarrhea, discomfort, and flatulence. However, repeated dose studies, such as Tetzloff et al. (1996) and others summarized in Table 12, demonstrate that ingestion of 1 g/kg bw of erythritol/day in five portions does not induce gastrointestinal symptoms. Thus, the gastrointestinal symptoms associated with erythritol ingestion can be attributed to the ingestion of a bolus of an osmotically active substance.

Table 12. Studies of Effect of Repeated Doses of Erythritol in Human Subjects

SUBJECTS	DOSE (G/KG BW)	RESULTS	REFERENCE
8 men, 2 women	20g 2x/day for 5 days, in water	No laxative effects observed, but 1 man reported upper GI pain & diarrhea on day 2 of study	Takahashi, 1992b
6 men	0.91/day for 3 days, in coffee	No GI effects reported. 3 men reported dryness or irritation of throat and/or stomach, thought to be due to high osmotic activity of coffee drink.	Hamada, 1996
8 men	0.86/day for 3 days, in tea	No adverse effects were reported.	Masuyama, 1996
12 men	2 day adaptation: 0.3; 5 day test period: 1	No adverse GI effects, no diuretic effects reported.	Tetzloff et al., 1996
3 male, 8 female NIDDM patients	20 g/day for 14 days	No adverse effects reported, but data not collected/reported for all patients	Miyashita et al., 1993 Ishikawa et al., 1996

3. Allergenicity Studies

Three well-described cases of allergy to erythritol have been described in humans (Hino, et al., 2000; Yunginger, et al., 2001). One man exhibited generalized urticaria or hypotension after erythritol ingestion, and two women developed generalized urticaria. No allergy or hypersensitivity to erythritol was found in rats (Kawauchi et al., 1989a) or guinea pigs (Kawauchi, et al., 1989b). In addition, no allergic symptoms were identified in humans in any of the clinical studies described above. Finally, erythritol occurs naturally in foods such as cheese, fruits, and chocolate, which are not known to be common allergens. The underlying cause of the described allergic reactions in humans remain obscure, and the estimated prevalence of allergic reaction to erythritol containing products is less than 1 per million people (Yunginger et al., 2001).

VI. DISCUSSION

A. GRAS Criteria

FDA defines "safe" or "safety" as it applies to erythritol as:

"...reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance."[13]

Amplification is provided in that the determination of safety is to include probable consumption of the substance in question, the cumulative effect of the substance and appropriate safety factors. It is FDA's operational definition of safety that serves as the framework against which this evaluation is provided.

Furthermore, in discussing GRAS criteria, FDA notes that:

"...General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food."

"General recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information."[14]

FDA discusses in more detail what is meant by the requirement of general knowledge and acceptance of pertinent information within the scientific community, i.e., the so-called "common knowledge element," in terms of the two following component elements:[15]

- Data and information relied upon to establish safety must be generally available, and this is most commonly established by utilizing published, peer-reviewed scientific journals; and

- There must be a basis to conclude that there is consensus (but not unanimity) among qualified scientists about the safety of the substance for its intended use, and this is established by relying upon secondary scientific literature such as published review articles, textbooks, or compendia, or by obtaining opinions of expert panels or opinions from authoritative bodies, such as JECFA and the National Academy of Sciences.

The apparent imprecision of the terms "appreciable", "at the time" and "reasonable certainty" demonstrates that FDA recognizes the impossibility of providing absolute safety in this or any other area (Lu, 1988; Renwick, 1990; Rulis and Levitt, 2009).

[13] See 21 CFR 170.3(i).
[14] See 21 CFR 170.30(a).
[15] See Footnote 1.

As noted below, this safety assessment to ascertain GRAS status for erythritol for the defined food uses meets FDA criteria for reasonable certainty of no harm by considering both the technical and common knowledge elements.

B. Safety of Erythritol

1. Expert & Regulatory Reviews

This notification relies upon published literature and data and information previously submitted to FDA to support its evaluations of erythritol in response to GRAS notifications 76 (FDA, 2001a) and 208 (FDA, 2006) and the Affirmation Petition filed jointly by Mitsubishi, Cerestar, and Nikken - GRASP No. 760422, 1997 (FDA, 2001a, p 126).

The scientific literature contains numerous safety studies supporting the safety of erythritol for food use. Extensive review articles on erythritol safety were published in 1996 (Bernt et al, 1996) and in 1998 (Munro et al, 1998) which discussed a variety of acute, subchronic and chronic studies in rats, mice and dogs. The review studies also included metabolic, reproduction, developmental and mutagenicity tests. These studies are reviewed in depth in Section V.

Erythritol has been used since 1990 in Japan as a component of candies, sugar substitutes, chocolates, soft drinks, chewing gum, jellies, jams, and yogurt (Bernt et al, 1996). Since 1996 there have been several affirmations of the safety of erythritol through regulatory processes.

> In December 1996, Cerestar Holding B.V. (Cerestar), Mitsubishi Chemical Corp. and Nikken Chemicals Co., Ltd. jointly submitted a GRAS affirmation petition which claimed GRAS status for erythritol when used in a variety of foods including sugar substitutes, hard and soft candies, chewing gum, and beverages.
>
> In 1997, FDA amended the health claim regulation regarding non-cariogenic carbohydrate sweeteners to include erythritol in response to this petition, and authorization of a health claim regarding erythritol indicates that the petitioners demonstrated to FDA's satisfaction that the substance is safe and lawful under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act, as mandated by 21 CFR 101.14(b)(3)(ii).[16]
>
> In 1999, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated erythritol and established an acceptable daily intake (ADI) "not specified."[17] The safety of erythritol is also supported by its chemical structure since erythritol is closely related to other common food ingredients such as sorbitol and mannitol. Ingested erythritol is significantly excreted unchanged in the urine and partially undergoes microbial fermentation to volatile fatty acids in the large intestine.

[17] ADI "not specified" is a term applicable to a food component of very low toxicity which, on the basis of the available chemical, biological, toxicological, and other data, indicates that the total dietary intake of the substance arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food, did not, in the opinion of the Committee, represent a hazard to health. For this reason and for those stated in the evaluation, the establishment of an ADI expressed in numerical form is deemed unnecessary.

The Cerestar Expert Panel reconvened in May 2000 to review expanded uses of erythritol that were also the subject of this GRAS notification. The Cerestar Panel concluded that under the conditions of the expanded uses in foods, erythritol meeting appropriate food grade specifications and manufactured in accordance with current good manufacturing practices, is GRAS.

In 2003, the Scientific Committee on Food (SCF) of the European Union issued an opinion on erythritol, concluding that its use as a food additive is acceptable and that a numerical ADI was not needed. On July 5, 2006, the European Union adopted a set of amendments to its food additive legislation authorizing the addition of erythritol to foods generally in accordance with good manufacturing practice. Under the Sweeteners Directive, erythritol is now authorized at *quantum satis* levels of use in a variety of foods, identical to the manner in which the other polyol sweeteners are authorized. Under the Miscellaneous Additives Directive, erythritol may be added to foods generally, except beverages, unprocessed foods, and certain other exceptions (but including liquors and including frozen, unprocessed fish, crustaceans, mollusks, and cephalopods) at *quantum satis* levels for purposes other than sweetening (Directive 2006/52/EC of the European Parliament and of the Council of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs. Official Journal of the European Union, L204/10,26 July 2006).[18]

FDA has reviewed two separate GRAS notifications involving microorganisms used for fermentation. In 2001, FDA responded favorably to GRN 76 in which Cerestar claimed that erythritol is GRAS under the same conditions of use covered by GRN 208 and the present submission (FDA, 2001b). Both microorganisms, *Trichosporonoides megachiliensis* and *Moniliella pollinis,* have been reviewed and found to be acceptable by JECFA, the SCF and the Committee on Food Chemicals Codex. As previously described, the fermentation broth containing erythritol is separated from the organisms and subjected to purification treatment similar to those for the carbohydrate sweeteners and sugar alcohols, e.g., ion-exchange resin, activated charcoal, and crystallization. The final product is a highly purified preparation of erythritol that meets the FCC specifications of not less than 99.5% erythritol.

2. Panel Findings

The Expert Panel, having reviewed the individual studies, the available comprehensive critical reviews, the international regulatory summaries, the FOA/WHO expert committee evaluations and previous GRAS submissions on erythritol, concluded that O'Laughlin's erythritol at the usage levels described herein is generally recognized as safe in foods.

The Expert Panel bases this conclusion on the following findings:

- **ADME studies** in mice rats, dogs and humans show that erythritol is almost completely absorbed in the small intestine and excreted unchanged in the urine.

[18] See DIRECTIVE 2006/52/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. Available online at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:204:0010:0022:EN:PDF.

There was no metabolic activation of erythritol in any of these studies, along with complete excretion provides a biological and physiological basis for the low toxicity noted in the studies below.

- **Animal toxicity studies** show erythritol displays a low order of toxicity in all animal testing yielding LD_{50} values in mice, rats and dogs >5 g/kg bw; NOAELs for subchronic dietary administration is 5% of the diet for all species which is equivalent to 7.5 g/kg bw/day in mice, 2.5 g/kg bw/day in rats, and 1.7 g/kg bw/day in dogs; chronic rat studies showed the NOEL was 2% of the diet based on increased water intake, cecal weights, and urine volume.

- **Subchronic and chronic animal studies** revealed no changes in hematological or clinical chemical parameters, organ weights or histopathology that were considered to be toxicologically significant or clinically relevant. Minor gastro-intestinal effects were observed in all orally administered studies which included transient laxation and soft stools, slight increases in BUN and urinary calcium; however, all of these effects were considered to be physiological or adaptive responses to the osmotic diuretic effects of absorbed erythritol.

- **Reproductive and/or developmental toxicity** was not observed at doses up to 8 g/kg bw/day in mice treated by gavage or at doses representing up to 10% (100 g/kg of the diet) in rats.

- **Genotoxicity and mutagenicity** studies have shown no *in vitro* mutagenesis or clastogenesis.

- **Carcinogenicity** was not evident in rats after 104 weeks with up to 10% in the diet.

- **Clinical studies** also show erythritol is well tolerated in humans, and it has a low order of toxicity with a single dose administration producing a NOEL for minor gastrointestinal symptoms such as diarrhea, discomfort and flatulence of 0.5-1.0 g/kg bw; repeated administration studies demonstrate that ingestion of 1 g/kg bw of erythritol/day in five portions does not induce gastrointestinal symptoms; allergenic studies estimate that allergic reactions occur in less than 1 in a million people.

- **The production process** is made from a sugar-rich substrate by fermentation with *Moniliella pollinis* which is a non-pathogenic and non-toxic yeast.

- Erythritol has a **long history of safe use.** It has been used as an ingredient in foods and beverages since 1990 in Japan (Bernt et al, 1996) and was approved by GRAS affirmations in 2001 (FDA, 2001a) and 2006 (FDA, 2006) which were accepted with agency response letters stating there were no questions about the safety claims in the notifications 2001 (FDA, 2001b) and in 2007 (FDA ,2007). It was approved for use in foods and beverages in Canada in November of 2004 (Canadian Gazette, 2004) and received full approval in the EU for use in foods in 2008 (Food Navigator, 2008). Overall, erythritol is sanctioned for use in the US, Canada, Mexico, Japan, the Philippines, Singapore and Taiwan (NewHope360, 2008).

C. Common Knowledge Elements of GRAS Determinations

The first common knowledge element for a GRAS determination is that data and information relied upon to establish safety must be generally available; this is most commonly established by utilizing published, peer-reviewed scientific journals for the safety assessment. The majority of the studies reviewed in this safety assessment have been published in the scientific literature as reported in Section V. The common use of erythritol in food on a global basis and the associated absence of harm is based upon published information of all types. In addition, the clinical studies, which support the safety assessment, have been published in the scientific literature.

Major critical reviews of well known experts in the field of food toxicology (e.g., Bernt et al, 1996; Munro et al, 1998) published comprehensive and critical reviews of the available data and information---both published and unpublished---and unanimously concluded that under the conditions of intended use in foods erythritol is GRAS based on scientific studies that each Panel reviewed. Most notably, the authors review two chronic studies there were performed with the determination that erythritol did not affect survival and was not carcinogenic at doses up to 10% of the diet (Til and van Nesselrooij, 1994; Lina et al, 1994, 1996).

In addition, clinical studies also show erythritol is well tolerated in humans and it has a low order of toxicity with single dose studies (Umeki, 1992; Takahashi, 1992a; Noda et al, 1994; Bornet et al, 1996a, b; Ishikama et al., 1996; Oku and Okazaki, 1996a, b; Storey et al, 2007) as well as repeated dose studies (Takahashi, 1992b; Hamada, 1996; Masuyama, 1996; Tetzloff et al., 1996; Miyashita et al., 1993; Ishikawa et al., 1996).

The second common knowledge element for a GRAS determination requires establishing that a consensus exists among qualified scientists about the safety of the substance with its intended use. As previously noted, in 1996 (Bernt et al, 1996) and in 1998 (Munro et al., 1998) literature reviews of all the available data were published in peer-reviewed publications both of which conclude that erythritol is GRAS. In December 1997, FDA approved a dental health claim for erythritol.[19]

Erythritol has been accepted as a safe sweeter by leading expert bodies including the Joint FAO/WHO Expert Committee on Food Additives (JECFA) which evaluated erythritol and assigned an Acceptable Daily Intake (ADI) "not specified" (JECFA, 1999). Subsequently, the European Commission – Health & Consumer Protection Directorate-General – Scientific Committee on Food (SCF, 2003) reviewed the body of data available on erythritol and concluded that the effects seen in the animal studies were attributable to physiological and adaptive responses to the rapid absorption and excretion of erythritol and to the osmotic activity of unabsorbed erythritol and its fermentation products in the gut. The intestinal effects were found to be common to all the polyols. The NOEL for the gastrointestinal laxative effect of erythritol in humans is approximately 0.5 g/kg bw for a single dose. The overall conclusion reached by the SCF was that erythritol is safe to use as a food additive. Concurring with an earlier JEFCA

[19] FDA dental health (61 FR 43446, Aug. 23, 1996, as amended at 62 FR 63655, Dec. 2, 1997); also see http://ecfr.gpoaccess.gov/cgi/t/text/text-idxc=ecfr;rgn=div5;view=text;node=21%3A2.0.1.1.2;idno=21;sid=64fa2cdef4ee54e80414c2f297540271;cc=ecfr#21:2.0.1.1.2.5.1.11..

opinion on other polyols, the Commission did not consider it appropriate to set a numerical Accepted Daily Intake (ADI) for erythritol.

Erythritol was approved for use in foods and beverages in Canada in November of 2004 (Canadian Gazette, 2004) and received full approval in the EU for use in foods in 2008 (Food Navigator, 2008). It has been used as an ingredient in foods and beverages since 1990 in Japan (Bernt et al, 1996) and was approved by the aforementioned GRAS affirmations in 2001 (FDA, 2001a) and 2006 (FDA, 2006) which were acknowledged and accepted by the US FDA in agency response letters stating there were no questions about the safety declarations in either notifications GRN 76 (FDA, 2001b) or GRN 208 (FDA, 2007).

The Expert Panel concludes that consensus exists regarding the safety of the intended human food uses of erythritol based upon the peer-reviewed literature including individual studies and critical general reviews; the Cerestar Holding B.V. Erythritol Expert Panel GRAS submission and the no questions agency response; the Mitsubishi-Kagaku Foods Corporation Erythritol Expert Panel GRAS submission and the no questions agency response, the numerous global regulatory agency approvals for use in food and beverages and the expert opinions by JECFA and the European Commission Scientific Committee on Food as well as regulatory bodies in the US, Canada, Mexico, Japan, the Philippines, Singapore and Taiwan all of which have concluded that erythritol is safe for use in food.

VII. CONCLUSIONS[20]

The Panel offers the following conclusion:

O'Laughlin's erythritol that is produced in accordance with FDA Good Manufacturing Practices requirements while meeting the purity specifications as set forth in Section III.E.2 of this notification is Generally Recognized As Safe when consumed as a flavor enhancer, formulation aid, humectant, stabilizer, sequestrant or nutritive sweetener in the food categories and at the designated food use levels as found in Table 5.

This declaration is made in accordance with FDA's standard for erythritol safety, i.e., reasonable certainty of no harm under the intended conditions of use.

(b) (6)

Richard C. Kraska, Ph.D., DABT
Chair

(b) (6)

Robert S. McQuate, Ph.D.

(b) (6)

Robert W. Kapp, Jr., Ph.D., Fellow ATS

September 9, 2011

[20] The detailed educational and professional credentials for two of the individuals serving on the Expert Panel can be found on the GRAS Associates website at www.gras-associates.com. Drs. Kraska and McQuate worked on GRAS and food additive safety issues within FDA's GRAS Review Branch earlier in their careers and subsequently continued working within this area in the private sector. Dr. Kapp's curriculum vitae can be accessed at http://www.biotox.net. All three panelists have extensive technical backgrounds in the evaluation of food ingredient safety. Each individual has previously served on multiple GRAS Expert Panels. Dr. Kraska served as Chair of the Panel.

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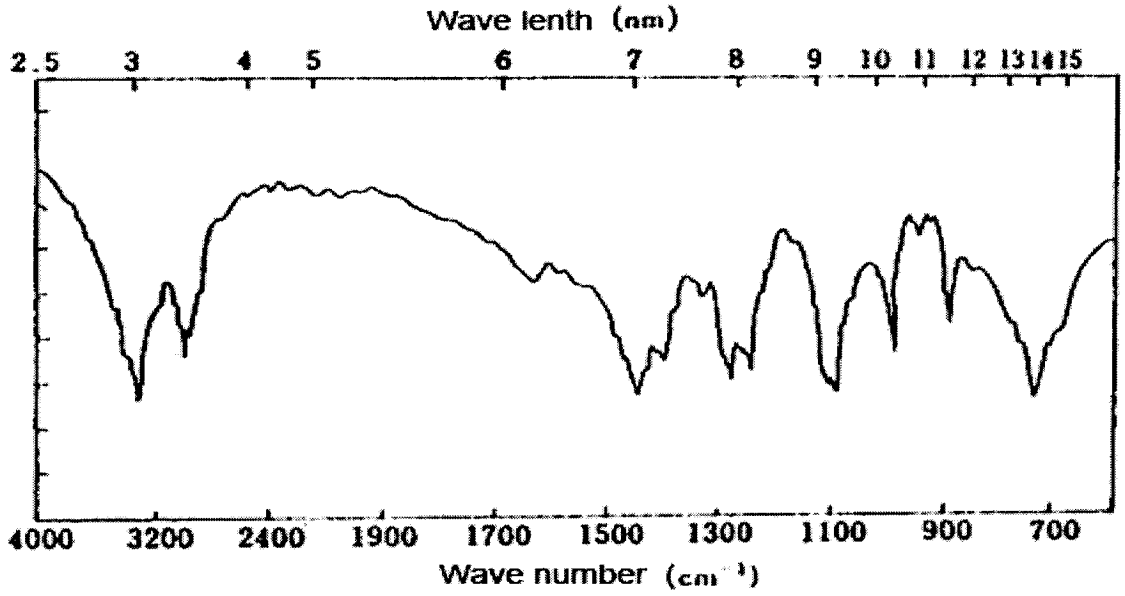
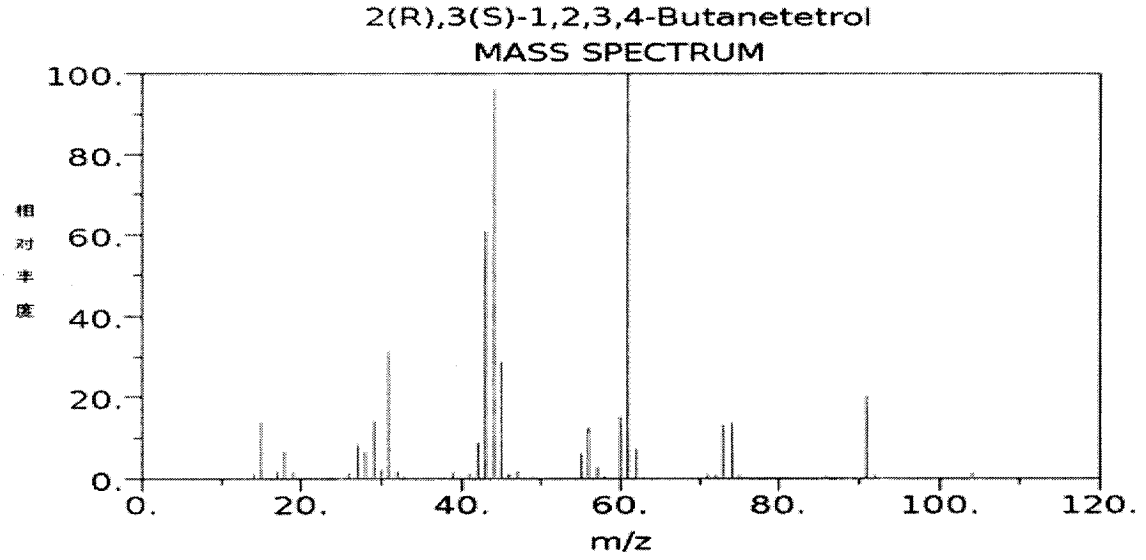
APPENDIX A

Chemical Properties of O'Laughlin's Erythritol

The Mass Spectra and Infrared Spectra of Erythritol



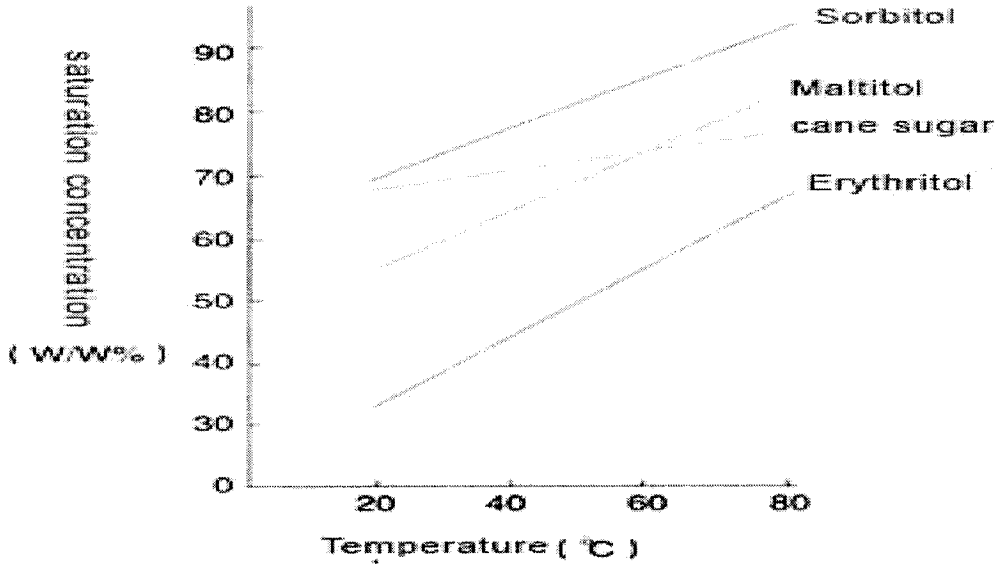
The Mass Spectrometry of Erythritol



Thermodynamic Data of Erythritol

Physical quantities	Value	Unit	Remarks
ΔfH°liquid: The standard enthalpy of formation in liquid state	-910.48 ± 0.54	kJ/mol Kilojoule/mole	
ΔcH°solid: The standard molar enthalpy of combustion in solid state	-2118	kJ/mol Kilojoule/mole	
S°solid,1 bar: The standard enthalpy of combustion in solid state under 1 bar pressure	166.5	J/mol*K Joule/mole*K	
Cp,solid: Heat capacity at constant pressure of solid material	161	J/mol*K Joule/mole*K	T = 30 to 150°C
Tboil	603.7	K	Boiling point
Tfus	390.9	K	Melting point
ΔvapH°: Enthalpy of vaporization (or Heat of vaporization)	93.3	kJ/mol Kilojoule/mole	
ΔsubH°: Enthalpy of sublimation	157	kJ/mol Kilojoule/mole	
ΔfusH: Melting enthalpy (or heat of fusion)	39.4	kJ/mol Kilojoule/mole	390.9K Below
ΔfusS: Change after the Entropy of fusion	100.8	J/mol*K Joule/mole*K	390.9K Below

The Solubility Situation of Erythritol



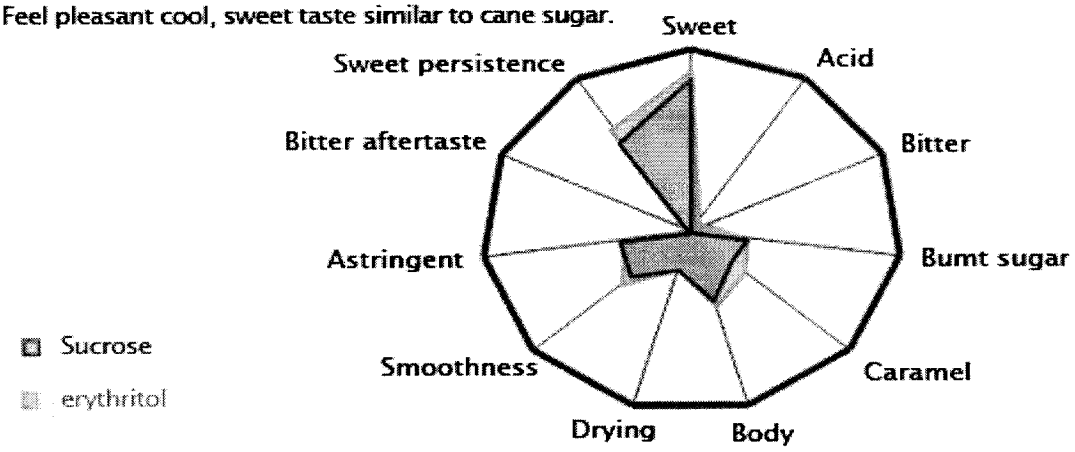
Solubility comparison for sweeteners

Solution heat of sweeteners against 25 distilled water

Saccharide	solution heat(cal/g)	relative solution heat (based on D-gluconse)
D-gluconse	-13.8	1
Cane sugar	-4.5	0.33
D-Sorbitol	-24.1	1.75
Erythritol	-42.9	3.12

The Sweet Taste Character of Erythritol

- 60%–70%: 60–70% sweet degree of cane sugar
- Feel pleasant cool, sweet taste similar to cane sugar.



APPENDIX B

Certifications

B-1 – Microorganism Identification

SGS

Test Report **No: TJFDO110601334FDE** **Date: Jul 15 2011**

Client name: o'laughlin(tianjin)industries co., ltd.
Client address: No27, Da Juan zi Industrial Zone, Jing Wu Town, Xi Qing District, Tian Jin, China

The following sample(s) was/were submitted by/ on behalf of the client as (except SGS Reference No. & SGS Job No. & Date of receipt & Testing period):

Sample name: 酵母菌
Batch No./Date: /
Manufacturer: /
SGS reference No.: SHFDO110713026FD
SGS job No.: TJFDO110601334FD
Date of receipt: Jul 01 2011
Testing period: Jul 01 2011 ~ Jul 13 2011

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
Microorganism identification

TEST METHOD(S):
SGS In house method – PCR)

TEST RESULT(S):

Test Item(s)	Test Method(s)	Test Result(s)
Microorganism identification	In house method – PCR	Moniliella pollinis

SAMPLE DESCRIPTION: The slant intube

Remark: This test report is in Chinese and maybe translated into other languages. The Chinese version shall prevail.

Signed for and on behalf of SGS

(b) (6)

Authorized Signature

*** End of Report***

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TJFD 009002

B-2 – Certification of Organism as non-GMO

SGS

Test Report **No: TJFDO100800833FD** **Date: Aug 20 2010**

Client name: O'Laughlin（Tianjin）Industries Co., Ltd.
Client address: No. 27th dajuanzi industrial Zone, Jingwu Town, Xiqing District, Tianjin China

The following sample(s) was/were submitted by/ on behalf of the client as:

Sample Name: ERYTHRITOL
Batch No./Date: 20100709-3/Jul. 09, 2010
Manufacturer: O'Laughlin（Tianjin）Industries Co., Ltd.
SGS Reference No: SHFDO100810853FD / AGL 1008-G-235(1)
SGS Job No: TJFDO100800833FD
Date of receipt: Aug 10 2010
Testing period: Aug 10 2010 ~ Aug 17 2010

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
Detection of genetically modified plant components

TEST METHOD(S):
SN/T 1202-2003 Protocol of the qualitative polymerase chain reaction for detecting genetically modified plant components in food

TEST RESULT(S):

Target Sequence	CaMV35S	NOS	Npt II	Reference gene*
Results	Not detected	Not detected	Not detected	Detected
Method Detection Limit	0.1%			

Remark:
DNA was isolated from the sample but target sequence CaMV35S, NOS, Npt II derived from GMO were not detected.

*Reference gene：reference gene is the endogenous gene of Eukaryotes and was used to measure the quality of the extracted DNA in the testing.

SAMPLE DESCRIPTION: White crystals in bag

Signed for and on behalf of SGS

(b) (6)

Authorized Signature

*** End of Report***

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Member of the SGS Group (SGS SA)

TJFD 003765

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Appendix B-3 – Certification of Membranes

证书编号：04709Q10288R1M

质量管理体系认证证书

(副本)

兹证明

杭州科诺过滤器材有限公司

注册地址：[illegible] 邮编：311404

生产地址：[illegible]

质量管理体系符合：

GB/T 19001-2008 idt ISO 9001:2008

一次性使用医用微孔滤膜、微孔滤膜、一次性使用过滤器、滤芯、一次性使用医用过滤器的设计开发、生产和服务。

初次日期：2009 年 09 月 [illegible]

有效期至：2012 年 09 月 [illegible]

陈志刚

北京国医械华光认证有限公司

CNAS

体系认证

CNAS C047 - Q

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

IAF

[illegible]

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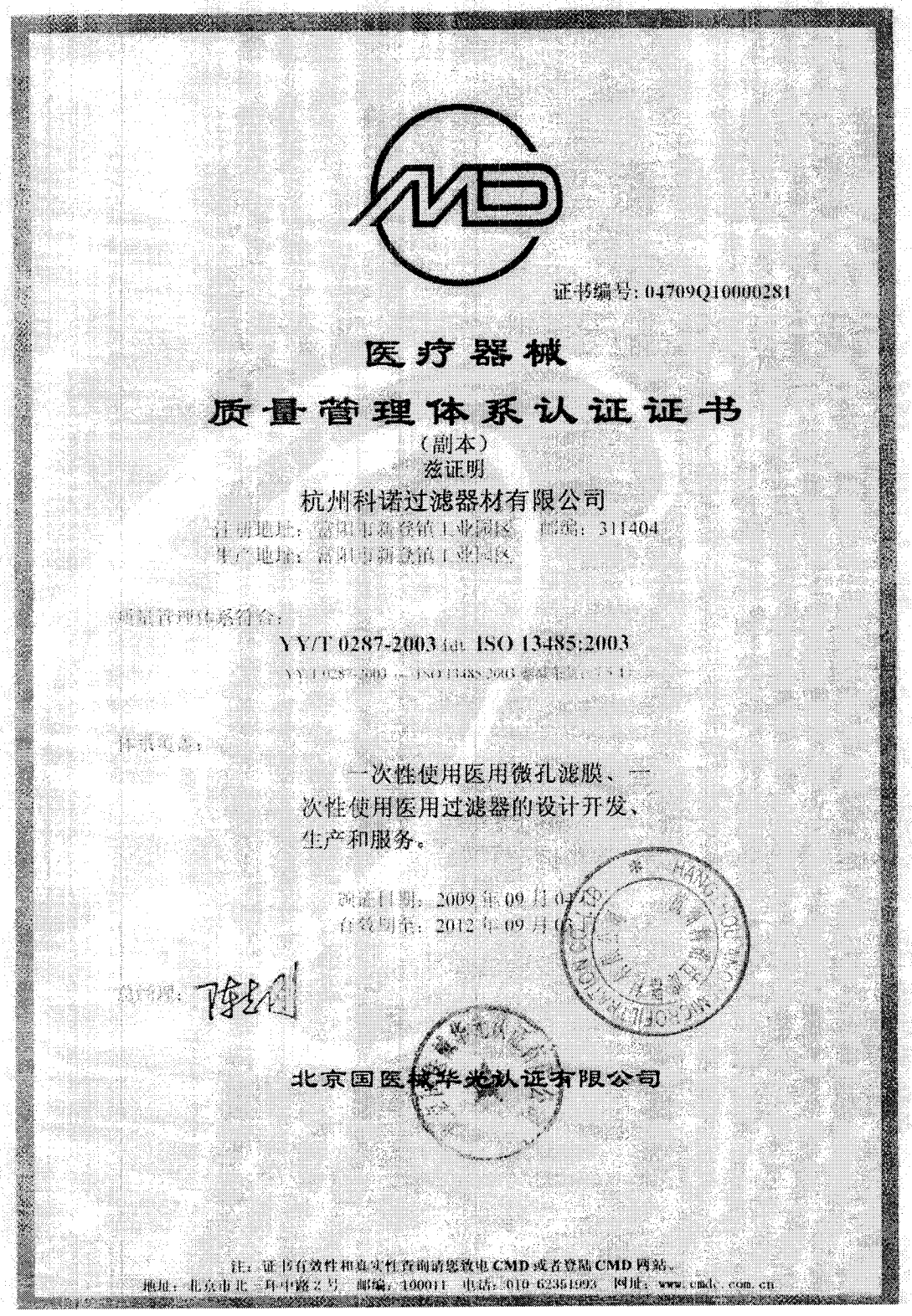
000052

Appendix B-3 – Certification of Membranes (continued)



证书编号：04709Q10000281

医疗器械

质量管理体系认证证书

（副本）

兹证明

杭州科诺过滤器材有限公司

注册地址：富阳市新登镇工业园区　邮编：311404

生产地址：富阳市新登镇工业园区

质量管理体系符合：

YY/T 0287-2003 idt. ISO 13485:2003

YY/T 0287-2003 idt. ISO 13485:2003

作出承诺：

一次性使用医用微孔滤膜、一次性使用医用过滤器的设计开发、生产和服务。

初证日期：2009 年 09 月 04 日

有效期至：2012 年 09 月 03 日

授权签字：陈生刚

北京国医械华光认证有限公司

注：证书有效性和真实性查询请您致电 CMD 或者登陆 CMD 网站。

地址：北京市北三环中路 2 号　邮编：100011　电话：010-62351993　网址：www.cmdc.com.cn

Appendix B-3 – Certification of Membranes (continued)

MEMBRANA
Underlining Performance

Your reference/Your letter	Our reference	Fon +49 (0) 2 02	Fax +49 (0) 2 02	Wuppertal
	Dr.Do/MM 6099-880			30.01.2003

CERTIFICATE

MicroPES Flat-Membranes
Type: 2F

1. Membrana's MicroPES flat membranes consist of high molecular weight Polyethersulfone (PES) and sulfonated Polyethersulfone.

   The raw material Polyethersulfone (CAS-No. 25667-42-9) complies fully with the Federal Food, Drug and Cosmetic Act and all applicable Food Additive Regulations, including 21 CFR §177.2440, "Polyethersulfone resins".

2. The membranes and their eluates meet the requirements of USP XXII, Cl. 6; <88> „Biological Reactivity Tests, in-vivo" and USP XXII <87> „Biological Reactivity Tests, in-vitro".

Membrana GmbH

(b) (6)

Dr.K.Dombrowski
(Quality Assurance)

(b) (6)

M.Rütering
(Key Account Manager)

Membrana GmbH
Oehder Str. 28
D-42289 Wuppertal
Germany
Fon +49 (0) 2 02 60 99-
Fax +49 (0) 2 02 60 57
www.membrana.com

Appendix B-3 – Certification of Membranes (continued)

INDUSTRIAL MEMBRANE SPECIALITIES

MEMBRANA
Underlining Performance

DATA SHEET

PRELIMINARY

DuraPES™

Hydrophilic flat membrane
Type 200

Intended use: Microfiltration

Sheet No. 468/0131/000 of 08/05
supersedes of

Chemical composition					**Test Ref.No:**
Polymer		Polyethersulfone			
Physical properties					
Thickness	m d	140 ± 10		µm µm	701/013
Tensile strength longitudinal transversal		 ≥ 550 ≥ 650		 cN/ 15 mm cN/ 15 mm	701/012
Elongation at break longitudinal transversal		 ≥ 15 ≥ 20		 % %	701/012
Change of length (steam, 121°C)	≤	3		%	701/027
Membrane performance characteristics					
Transmembrane flow (water, 25°C)	≥	45		ml/[min x cm² x bar]	701/046
Bubble point (water, 25°C)	m d	4.8 ± 0.5		bar bar	701/008
Retention of bacteria (Brevundimonas diminuta)	≥	7		log red. value	713/0.0001
Available make-up configurations					
	Rolls				

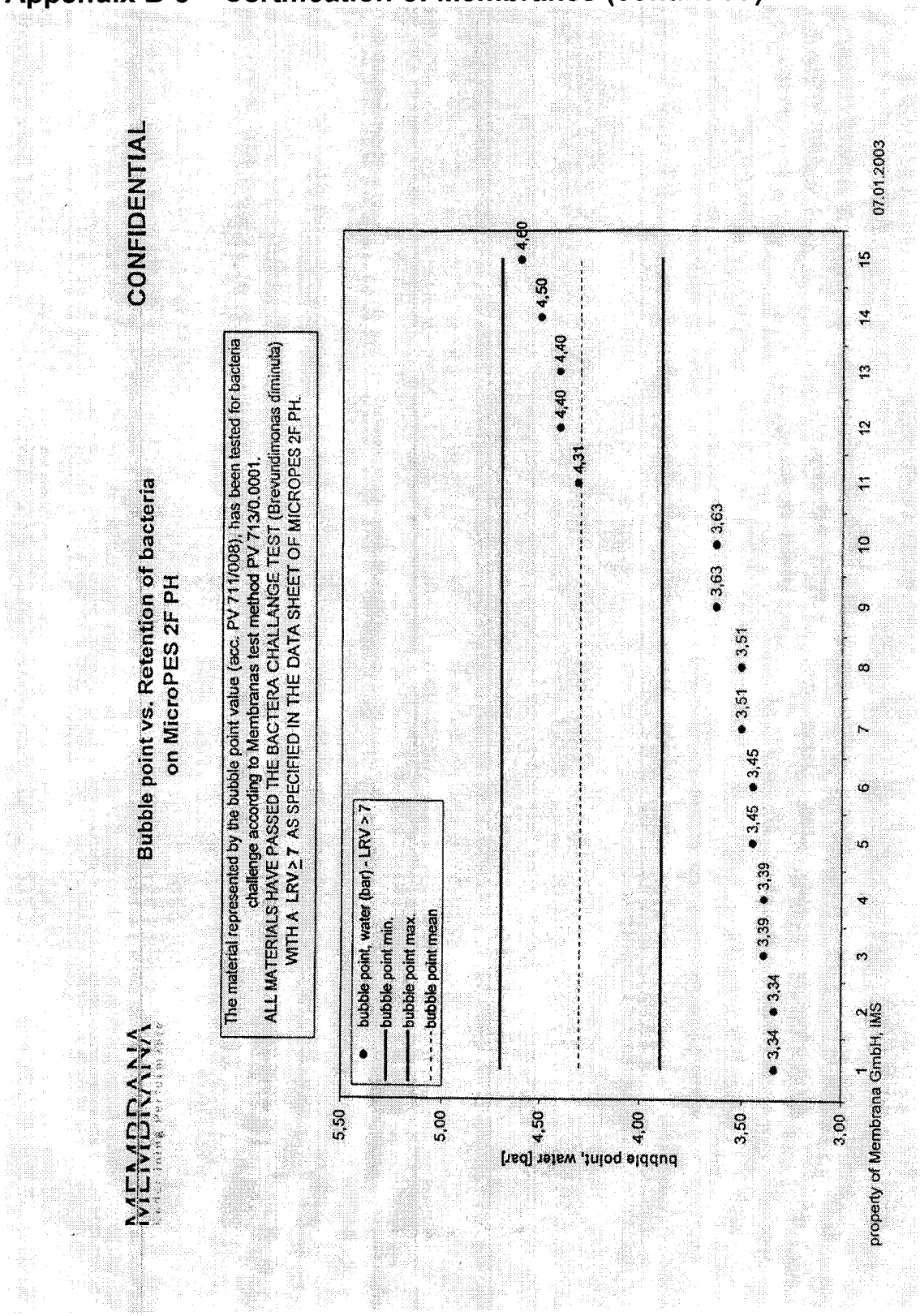
The information contained in this data sheet reflects the company's knowledge and experience at the time of issue. No guarantee can, however, be given as to its completeness. Neither must it be construed to embody any liability on the part of Membrana GmbH beyond the company's "General Conditions of Sale".
This product is delivered non-sterile.

m = mean value; d = deviation of the mean value;

Membrana GmbH
Oehder Straße 28, D – 42289 Wuppertal, Germany
Postal address: Postfach 20 01 51, D – 42201 Wuppertal
Phone (+49) (202) 6099-1
Fax (+49) (202) 60 70 296
www.membrana.com

A POLYPORE Company

Appendix B-3 – Certification of Membranes (continued)



Appendix B-3 – Certification of Membranes (continued)

MEMBRANA
Underlining Performance

• 磺化聚醚砜(Micro PES)平板微孔膜的性能：

商品号: Micro PBS	1F PH	1F BL	2F	2Fiv	4F	5F	6F	8F	12F
膜材料	聚醚砜（Sulfonated Polyethersulfone）								
膜厚度(μm)	110±10								
断裂强度 (厘牛顿/15mm)	纵>800 横>700		纵>900 横>800						
断裂伸长率(%)	纵>25% /横>30%								
121℃蒸汽下长度变形率	<3%								
破膜压力(bar)	>1.0bar								
膜性能参数	1F PH	1F BL	2P	2Fiv	4P	5P	6F	8F	12P
膜大孔径(μm)	0.3	0.3	0.48	0.48	0.69	0.9	1.09	1.48	1.97
泡点压力(水)(bar)	2.8± 0.21IPA	2.06± 0.21IPA	4.3± 0.54	4.3± 0.54	3.0± 0.25	2.2± 0.25	1.90± 0.42	1.40± 0.25	1.05± 0.25
对细菌去除率（按log[去除细菌数量]计）	>7.0	—	>7.0		—		>7.0	—	—
实验用菌种	无胆 原体氟	—	缺陷假单胞菌		格氏沙雷氏菌		—	糖化酵母	—
透水量[ml/(m²·hr·bar)]	> 2.4	>3.6	>21	>27	>36	>54.0	>54.0	>147	>136
产品包装(卷)	每卷长 200m×宽 0.254m，面积 50.8 m²								

中国总代理：大连欧科膜技术工程有限公司　　电话：0411-4509181　4509210　　传真：0411-4509220
地址：大连市西安路 90 号厂来大厦 12F-2　　邮编：116021

Appendix B-4 – Certification of Erythritol

SGS

Test Report **No: TJFDO110601394FDS1** **Date: Jul 20 2011**

Client name: o'laughlin(tianjin)industries co.,ltd.
Client address: No27, Da Juan zi Industrial Zone, Jing Wu Town, Xi Qing District, Tian Jin, China

The following sample(s) was/were submitted by/ on behalf of the client as (except SGS Reference No. & SGS Job No. & Date of receipt & Testing period):

Sample name: Erythritol
Batch No.: 2011062024
Manufacturer: o'laughlin(tianjin)industries co.,ltd
SGS Reference No.: SHFDO110713108FD
SGS Job No.: TJFDO110601394FD
Date of receipt: Jun 28 2011
Testing period: Jun 28 2011 – Jul 08 2011

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
Chemical testing: Assay, Lead (Pb), Loss on drying, Reducing sugars, Sulfated ash

TEST METHOD(S):
Assay: FCC V
Lead (Pb): In house method (ICP/MS)
Loss on drying, Reducing sugars: FCC VII
Sulfated ash: FCC VI

TEST RESULT(S):
Please refer to the next page

SAMPLE DESCRIPTION: White powder in bag

Signed for and on behalf of SGS

(b) (6)

Authorized Signature

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中国·天津市经济技术开发区第五大街41号SGS大厦 邮编: 300457 t (86-22) 65288239 f (86-22) 65288133 e sgs.china@sgs.com

TJFD 009163

Appendix B-4 – Certification of Erythritol (continued)

SGS

Test Report **No: TJFDO110601394FDS1** **Date: Jul 20 2011**

TEST RESULT(S):
Chemical testing

Test item	Test method	Test result	Standard of FCC VII	Single Determination
Assay %	FCC V	99.5	99.5-100.5	Conform
Lead (Pb) mg/kg	In house method (ICP/MS)	< 0.05	< 1	Conform
Loss on drying %	FCC VII	0.068	< 0.2	Conform
Reducing sugars %	FCC VII	< 0.3	< 0.3	Conform
Sulfated ash %	FCC VI	0.03	< 0.1	Conform

*** End of Report***

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TJFD 003162

B-5 – Certification of Dextrose

SGS

Test Report **No: TJFDO110801934FDS1** **Date: Aug 24 2011**

Client name: O'Laughlin(TianJin)Biotechnology Company
Client address: No.27 Da Juan zi Industrial Zone, Jing Wu Town, Xi Qing District, Tian Jin, China

The following sample(s) was/were submitted by/ on behalf of the client as (except SGS Reference No. & SGS Job No. & Date of receipt & Testing period):

Sample name: Dextrose
Batch No./Date: 11061131
Manufacturer: Shangdong Xiwang Bio-chem Technology Co.Ltd
SGS reference No.: SHFDO110816399FD
SGS job No.: TJFDO110801934FD
Date of receipt: Aug 05 2011
Testing period: Aug 05 2011 ~ Aug 16 2011

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
Specific rotation, Sulfur Dioxide, Assay, Arsenic (As), Lead (Pb), Sodium Chloride, Loss on drying, Residue on Ignition, Starch

TEST METHOD:
Specific rotation, Sulfur Dioxide, Assay, Sodium Chloride, Loss on drying, Residue on Ignition, Starch: Food Chemicals Codex Fifth Edition
Arsenic (As), Lead (Pb): In house method (ICP/MS)

TEST RESULT(S):
Please refer to the next page

SAMPLE DESCRIPTION: Sample in bag

Signed for and on behalf of SGS

(b) (6)

Authorized Signature

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Appendix B-5 – Certification of Dextrose (continued)

SGS

Test Report **No: TJFDO110801934FDS1** **Date: Aug 24 2011**

TEST RESULT(S):

Test item(s)	Test method(s)	Test result(s)	Method detection limit(s)	Standard of FCC V	Single Determination
Sulfur Dioxide %	FCC V	Not detected	0.001	< 0.002	Conform
Specific rotation $[\alpha]_D^{25}$	FCC V	+ 53.1°	/	+ 52.6° ~ + 53.2°	Conform
Assay %	FCC V	99.8	/	99.5 ~ 100.5	Conform
Arsenic (As) mg/kg	In house method (ICP/MS)	Not detected	0.05	< 1	Conform
Lead (Pb) mg/kg	In house method (ICP/MS)	0.08	0.05	< 0.1	Conform
Sodium Chloride %	FCC V	< 0.018	/	< 0.018	Conform
Loss on drying %	FCC V	8.28	/	< 10.0	Conform
Residue on Ignition %	FCC V	0.044	/	< 0.1	Conform
Starch	FCC V	Pass	/	Pass	Conform

*** End of Report***

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TJFD 010495

B-6 – Certification of HCl

SGS

Test Report **No: TJFDO110601402FDS1** **Date: Jul 20 2011**

Client name: o'laughlin(tianjin)industries co., ltd.
Client address: No.27 Da Juan zi Industrial Zone, Jing Wu Town, Xi Qing District, Tian Jin, China

The following sample(s) was/were submitted by/ on behalf of the client as (except SGS Reference No. & SGS Job No. & Date of receipt & Testing period):
Sample name: hydrochloric acid
Batch No./Date: 20110509
Manufacturer: Befar Group Co., Ltd
SGS reference No.: TSNFD1110067101
SGS job No.: TJFDO110601402FD
Date of receipt: Jun 28 2011
Testing period: Jun 28 2011 ~ Jul 15 2011

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
Assay, Iron, Lead, Mercury, Oxidizing Substances(As Cl_2), Reducing Substances(As SO_3) , Sulfate, Nonvolatile residue

TEST METHOD(S):
Assay, Oxidizing Substances(As Cl_2), Reducing Substances(As SO_3), Sulfate, Nonvolatile residue
FCC VII
Iron, Mercury: In house method(ICP-MS)
Lead: In house method(ICP-OES)

TEST RESULT(S):

Test Item(s)	Test Method(s)	Test Result(s)	Standard of FCC VII	Single Determination
Assay %	FCC VII	103	97-103	Conform
Iron mg/kg	In house method(ICP-MS)	<0.05	<5	Conform
Mercury mg/kg	In house method(ICP-MS)	<0.05	<0.1	Conform
Lead mg/kg	In house method(ICP-OES)	<0.1	<1	Conform
Oxidizing Substances (As Cl_2) %	FCC VII	<0.003	<0.003	Conform
Reducing Substances (As SO_3) %	FCC VII	<0.007	<0.007	Conform
Sulfate %	FCC VII	<0.5	<0.5	Conform
Nonvolatile residue %	FCC VII	<0.5	<0.5	Conform

SAMPLE DESCRIPTION: Liquid in bottle

Signed for and on behalf of SGS

(b) (6)

Authorized Signature

*** End of Report***
Page 1 of 1

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Member of the SGS Group (SGS SA)

TJFD 009159

B-7 – Certification of NaOH

SGS

Test Report **No: TJFDO110601403FDS1** **Date: Jul 20 2011**

Client name: o'laughlin(tianjin)industries co., ltd.
Client address: No.27 Da Juan zi Industrial Zone, Jing Wu Town, Xi Qing District, Tian Jin, China

The following sample(s) was/were submitted by/ on behalf of the client as (except SGS Reference No. & SGS Job No. & Date of receipt & Testing period):

Sample name: Sodium Hydroxide
Batch No./Date: 20110526
Manufacturer: Befar Group Co., Ltd
SGS reference No.: TSNFD111006401
SGS job No.: TJFDO110601403FD
Date of receipt: Jun 28 2011
Testing period: Jun 28 2011 ~ Jul 15 2011

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
Assay, Arsenic, Mercury, Aluminum, Carbonate(as Na_2CO_3)

TEST METHOD(S):
Assay, Carbonate (as SO_3): FCC VII
Arsenic, Mercury: In house method(ICP-MS)
Lead: In house method(ICP-OES)

TEST RESULT(S):

Test Item	Test Method	Test Result	Standard of FCC VII	Single Determination
Assay %	FCC VII	95.1	95 -100.5	Conform
Arsenic mg/kg	In house method (ICP-MS)	< 0.05	< 3	Conform
Mercury mg/kg	In house method (ICP-MS)	< 0.05	< 0.1	Conform
Lead mg/kg	In house method (ICP-OES)	< 2	< 2	Conform
Carbonate (as SO_3) mg/kg	FCC VII	2.2	< 3.0	Conform

SAMPLE DESCRIPTION: Liquid in bottle

Signed for and on behalf of SGS

(b) (6)

Authorized Signature

*** End of Report***

Page 1 of 1

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中国·天津市经济技术开发区第五大街41号SGS大厦 邮编: 300457 t (86-22) 65288239 f (86-22) 65288133 e sgs.china@sgs.com
Member of the SGS Group (SGS SA)

TJFD 009158

B-8 – Certification of Diammonium Phosphate

SGS

Test Report **No: TJFDO110601405FDS1** **Date: Jul 20 2011**

Client name: o'laughlin(tianjin)industries co., ltd.
Client address:No 27 Da Juan zi Industrial Zone, Jing Wu Town, Xi Qing District, Tian Jin, China

The following sample(s) was/were submitted by/ on behalf of the client as (except SGS Reference No. & SGS Job No. & Date of receipt & Testing period):

Sample name: Diammonium Phosphate
Batch No./Date: 20110520
Manufacturer: TIANJIN RONGHONG CHEMICAL CO., LTD
SGS job No.: TJFDO110601405FD
Date of receipt: Jun 28 2011
Testing period: Jun 28 2011 ~ Jul 06 2011

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
Assay, Lead, Fluoride, Arsenic

TEST METHOD(S):
Assay, Fluoride: FCC VII
Lead, Arsenic: In house method(ICP-MS)

TEST RESULT(S):

Test Item	Test Method	Test Result	Standard of FCC VII	Single Determination
Assay %	FCC VII	99.1	96-102	Conform
Lead mg/kg	ICP-MS	< 0.05	< 4	Conform
Arsenic mg/kg	ICP-MS	< 0.05	< 3	Conform
Fluoride mg/kg	FCC VII	8.1	< 10	Conform

SAMPLE DESCRIPTION: White crystal powder in bag

Signed for and on behalf of SGS

(b) (6)

Authorized Signature

*** End of Report***

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TJFD 009156

B-9 – Certification of Magnesium Sulfate

SGS

Test Report **No: TJFDO110601404FDS1** **Date: Jul 20 2011**

Client name: o'laughlin(tianjin)industries co., ltd.
Client address:No.27 Da Juan zi Industrial Zone, Jing Wu Town, Xi Qing District, Tian Jin, China

The following sample(s) was/were submitted by/ on behalf of the client as (except SGS Reference No. & SGS Job No. & Date of receipt & Testing period):

Sample name: Magnesium Sulfate
Batch No./Date: 11032301
Manufacturer: Lianyungang Dikang Food Additive Factory
SGS job No.: TJFDO110601404FD
Date of receipt: Jun 28 2011
Testing period: Jun 28 2011 ~ Jul 04 2011

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
Assay, Lead, Selenium, Loss on ignition

TEST METHOD(S):
Assay, Loss on ignition: FCC VII
Lead, Selenium: In house method(ICP-MS)

TEST RESULT(S):

Test Item	Test Method	Test Result	Standard of FCC VII	Single Determination
Assay %	FCC VII	99.9	> 99.5	Conform
Lead mg/kg	ICP-MS	< 0.05	< 4	Conform
Selenium mg/kg	ICP-MS	< 0.05	< 30	Conform
Loss on ignition %	FCC VII	49.5	40-52	Conform

SAMPLE DESCRIPTION: white crystal powder in bag

Signed for and on behalf of SGS

(b) (6)
Authorized Signature

*** End of Report***

Page 1 of 1

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中国·天津市经济技术开发区第五大街41号SGS大厦 邮编: 300457 t (86-22) 65288239 f (86-22) 65288133 e sgs.china@sgs.com

TJFD 009157

B-10 – Certification of Yeast Extractive

SGS

Test Report **No: TJFDO110801933FD** **Date: Aug 17 2011**

Client name: O'Laughlin(TianJin)Biotechnology Company
Client address: No27, Da Juan zi Industrial Zone, Jing Wu Town, Xi Qing District, Tian Jin, China

The following sample(s) was/were submitted by/ on behalf of the client as (except SGS Reference No. & SGS Job No. & Date of receipt & Testing period):

Sample name: Yeast extractive
Batch No.: 2011020502C6
Manufacturer: Angel Yeast Co. Ltd
SGS Job No.: TJFDO110801933FD
Date of receipt: Aug 03 2011
Testing period: Aug 03 2011 ~ Aug 16 2011

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
Microbial testing: Total Plate Count, Coliforms, Salmonella spp, Mould & Yeast
Chemical testing: Assay, Mercury (Hg), Lead (Pb), Ammonia Nitrogen, Insoluble residue, Potassium (K), Sodium Chloride

TEST METHOD(S):
Total Plate Count: FDA/BAM online chapter 3
Coliforms: FDA/BAM online chapter 4
Salmonella spp: FDA/BAM online chapter 5
Mould & Yeast: FDA/BAM online chapter 18
Assay, Ammonia Nitrogen, Insoluble residue, Potassium (K), Sodium Chloride: FCC VII
Mercury (Hg), Lead (Pb): In house method (ICP/MS)

TEST RESULT(S):
Please refer to the next page

SAMPLE DESCRIPTION: Light brown powder in bag

Signed for and on behalf of SGS

(b) (6)

Authorized Signature

SGS-CSTC Standards Technical Services (Tianjin) Co. Ltd.
Food Laboratory
SGS Mansion, No. 41, The 5th Avenue TEDA, Tianjin, China 300457 t (86-22) 65288239 f (86-22) 65288133 www.cn.sgs.com
中国·天津市经济技术开发区第五大街41号SGS大厦 邮编: 300457 t (86-22) 65288239 f (86-22) 65288133 e sgs.china@sgs.com
Member of the SGS Group (SGS SA)

TJFD 011791

B-10 – Certification of Yeast Extractive (continued)

SGS

Test Report **No: TJFDO110801933FD** **Date: Aug 17 2011**

TEST RESULT(S):

Microbial testing:

Test item	Test method	Test result	Standard of FCC VII	Single Determination
Total Plate Count cfu/g	FDA/BAM online chapter 3	2.7×10^4	$<5\times10^4$	Conform
Coliforms cfu/g	FDA/BAM online chapter 4	< 10	< 10	Conform
Salmonella spp. /25g	FDA/BAM online chapter 5	Negative	Negative	Conform
Mould & Yeast cfu/g	FDA/BAM online chapter 18	M < 10 Y < 10	< 50	Conform

Chemical testing:

Test item	Test method	Test result	Standard of FCC VII	Single Determination
Assay %	FCC VII	46.1	> 42	Conform
Mercury (Hg) mg/kg	In house method (ICP/MS)	< 0.05	< 3	Conform
Lead (Pb) mg/kg	In house method (ICP/MS)	0.29	< 2	Conform
Ammonia Nitrogen %	FCC VII	1.9	< 2	Conform
Insoluble residue %	FCC VII	< 0.1	< 2	Conform
Potassium (K) %	FCC VII	2.47	< 13	Conform
Sodium Chloride %	FCC VII	0.09	< 50	Conform

*** End of Report***

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中国·天津市经济技术开发区第五大街41号SGS大厦 邮编: 300457 t (86-22) 65288239 f (86-22) 65288133 e sgs.china@sgs.com

TJFD 011790

B-11 – Certification of GMP Codex Alimentarius for O'Laughlin Facility

SGS

Certificate CN09/00089gm

The management system of

O' Laughlin (Tianjin) Industries Co., Ltd

Kuan He Village Nan He Town Xi Qing Dist, Tianjin, P. R. China

SYSTEM CERTIFICATION SGS

has been assessed and certified as meeting the requirements of

GMP Codex Alimentarius
General Principles of Food Hygiene
CAC/RCP-1-1969, Rev. 4(2003)

For the following activities

Manufacture of xylitol.

Further clarifications regarding the scope of this certificate and the applicability of GMP requirements may be obtained by consulting the organization

This certificate is valid from 04 May 2009 until 03 May 2012
Issue (1). Certified since May 2009

(b) (6)

Authorised by

APPENDIX C

Manufacturing Process & Flow Chart of Erythritol

4.3.2 Description of production process of erythritol

4.3.2.1 package materials procurement: polyethylene inner bag and composite bags buy from the manufacturers who have FCC package producing license and have passed our inspection and already approved by our company.

4.3.2.2 auxiliary materials storage: store according to the nature of their usage

4.3.2.3 Main material oral glucose purchase from approved suppliers and inspect according to product standards.

4.3.2.4 dissolving: put water in sugar bowl, then put glucose in, blending to dissolve completely.

4.3.2.5 first culture: first culture of bacteria means broaden culture of bacteria of the 500L seed pot in plant based on the Proliferation Culture of two grade Erlenmeyer flasks rotary shaker, the purpose is to supply high quality liquid bacteria seed for second seed pot

4.3.2.6 Second culture: second culture of bacteria means purify and broaden culture of bacteria further for the 500L seed pot based on the first culture, the purpose is to supply high quality liquid bacteria seed for 80m3 Fermentation pot.

4.3.2.7 third culture:

4.3.2.8 Fermentation: broaden culture for the liquid bacteria seed from second seed pot and then go to ferment in 150m3 and 180m3 fermentation pot, and then get the fermentation liquid of erythritol

4.3.2.9 inactivation: inactivated in high temperature after fermentation

4.3.2.10 bacteria filtration: in this process, extract mycelium from erythritol fermentation liquid by frame filter press, recycle after get rid of water.

4.3.2.11 First Decolorization: add diatomite filter aid and activated charcoal in filtrate for decolor

4.3.2.12 frame filteration: remove diatomite filter aid and activated charcoal from first decolored liquid by frame filter press, then put into second decolorization pot

4.3.2.13 Second Decolorization, add activated charcoal in second decolorization pot to decolor.

4.3.2.14 frame filteration, remove activated charcoal

4.3.2.15 ion exchange: ion exchange mainly removes the inorganic salt, pigment and organic impurities from the liquid. The erythritol liquid come to buffer tank, enter anion exchange column, then cations exchange column, then anion exchange column, control electric conductivity $\leq 100\,\mu$ s/cm

4.3.2.16 evaporation and concentration: this process is to improve the concentration of erythritol to technical requirement. The erythritol liquid concentrated in vacuum evaporation, the concentration

improved to 50～70BX.

4.3.2.17 First crystallization: down the temperature to 55° C by Plate-shell heat exchanger before add the material to crystallization pot, control suitable oversaturation to crystallize. In order to guarantee the quality and quantity of the crystal, we need to add seed crystal. Cooling to keep the oversaturation after get crystal, crystal yield around 50-55%

4.3.1.18 First separation: the material is composited by erythritol and mother liquor, separate them by centrifuge. Mother liquor separated from erythritol crystal in the centrifugal effect, and collects the mother liquor to pot, crystals automatically discharging after cleaned by pure water. After the mother liquor is concentrated through evaporation it will be crystallized through mother liquor crystallization system, and the mother liquor crystal obtained will be analyzed, the high-purity mother liquor crystal will return to the dissolution procedures and the low-purity mother liquor crystal will return to concentration procedure before evaporation.

4.3.1.19 Dissolving alcohol: the crystals come from centrifuge convey to alcohol-dissolved pot by screw conveyer, add the second separated mother liquor or pure water, dissolving.

4.3.1.20 Third decolorization: the purpose is to remove colored materials that produced by high temperature in dissolved alcohol and evaporation materials, and improve filtering speed. Add materials to decolorization pot, decolor time 30 minites.

4.3.1.21 frame filteration, primary filtering and inspecting filtering by two frame filter presses

4.3.1.22 Precise filtration: alcohol liquor convey to evaporation crystallization process by 1micron precise filter after the third decolorization and filtration.

4.3.1.23 Second crystallization: put erythritol into crystallizer after evaporating, add suitable seed crystals, and concentrating, erythritol liquid gradually crystallize and grow up. The process needs 6-10 hours.

4.3.2.24 separation process: materials is composited by erythritol and mother liquor, separate them by centrifuge, collects mother liquor and water to second mother liquir pot. Crystals automatically discharge after cleaning by pure water and evaporating water. The eryhritol crystals then come to the process of drying and package.

4.3.2.25 Drying process: we use Boiling Bed and Vibrated Fluidized Bed, drying crystal by hot no-bacterium air, and cooling by cool no-bacterium air in Vibrated Fluidized Bed, after that, the moisture of crystal under 0.2%

4.3.2.26 permanent magnet grate, after a 9000 gauss permanent magnet grate and a 12000 gauss permanent magnet grate, the products convey to storehouse by screw conveyor

4.3.2.27 package inspection (25kgs/bag): in GMP standard package room, put the inner bag in outer bag, inspect every inner bags and outer bags, after package leader approve the package, disinfect in disinfection cabinet

4.3.2.28 container bag inspection: In the GMP standard package room, open every container bags to inspect if any foreign objects. After approved by package leader, disinfecting in disinfection cabinet

4.3.2.29 Packing: the materials go through metal remover and electronic weigher charging hole into 25kgs bags or container bags (if the materials have metal, it will automatically go to another discharging hole and put into the waste bags). Bags will automatically fall after reach the setting weight..

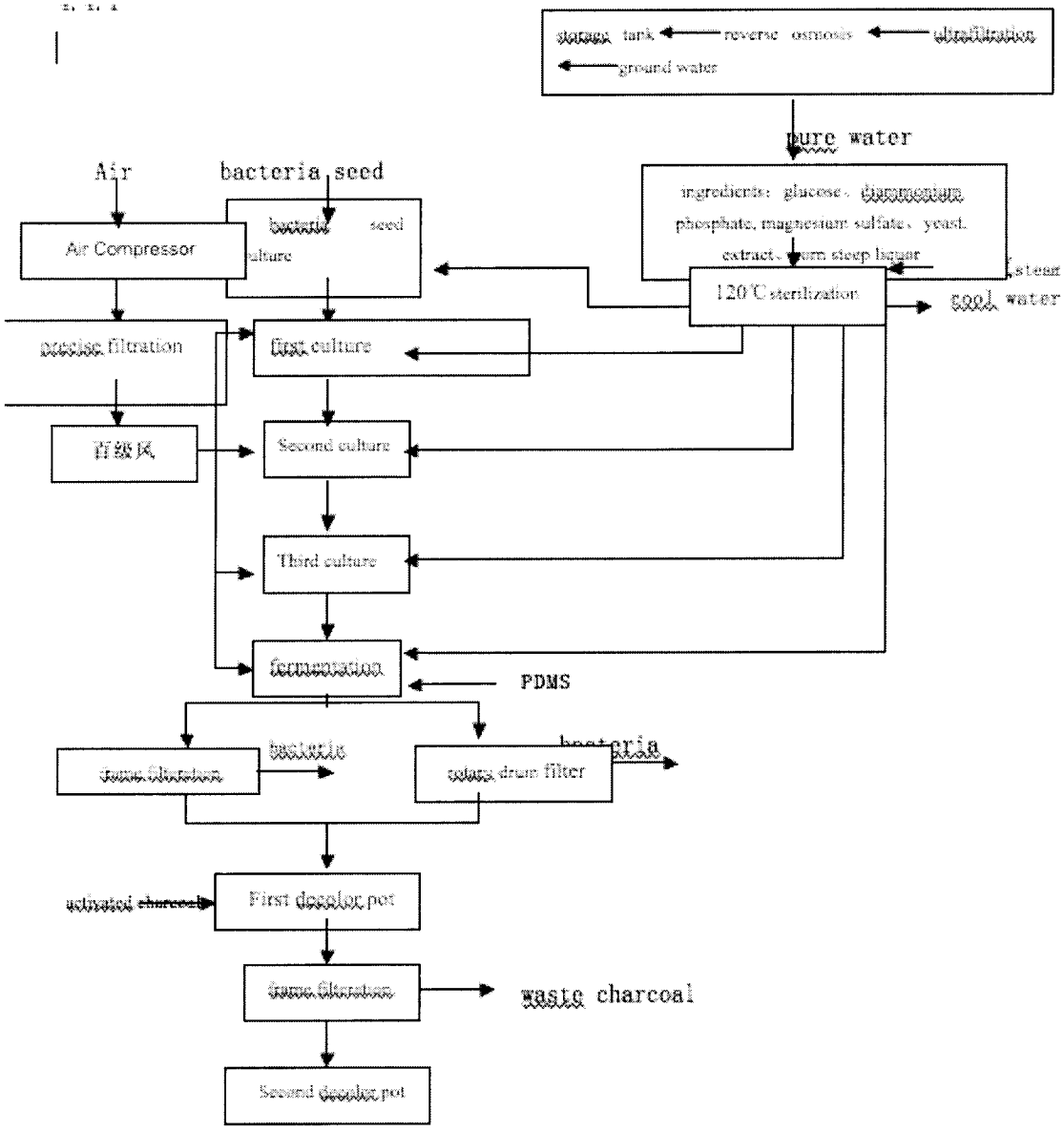
4.3.2.30 Re-Weighing: Re-weighing after confirm no foreign objects.

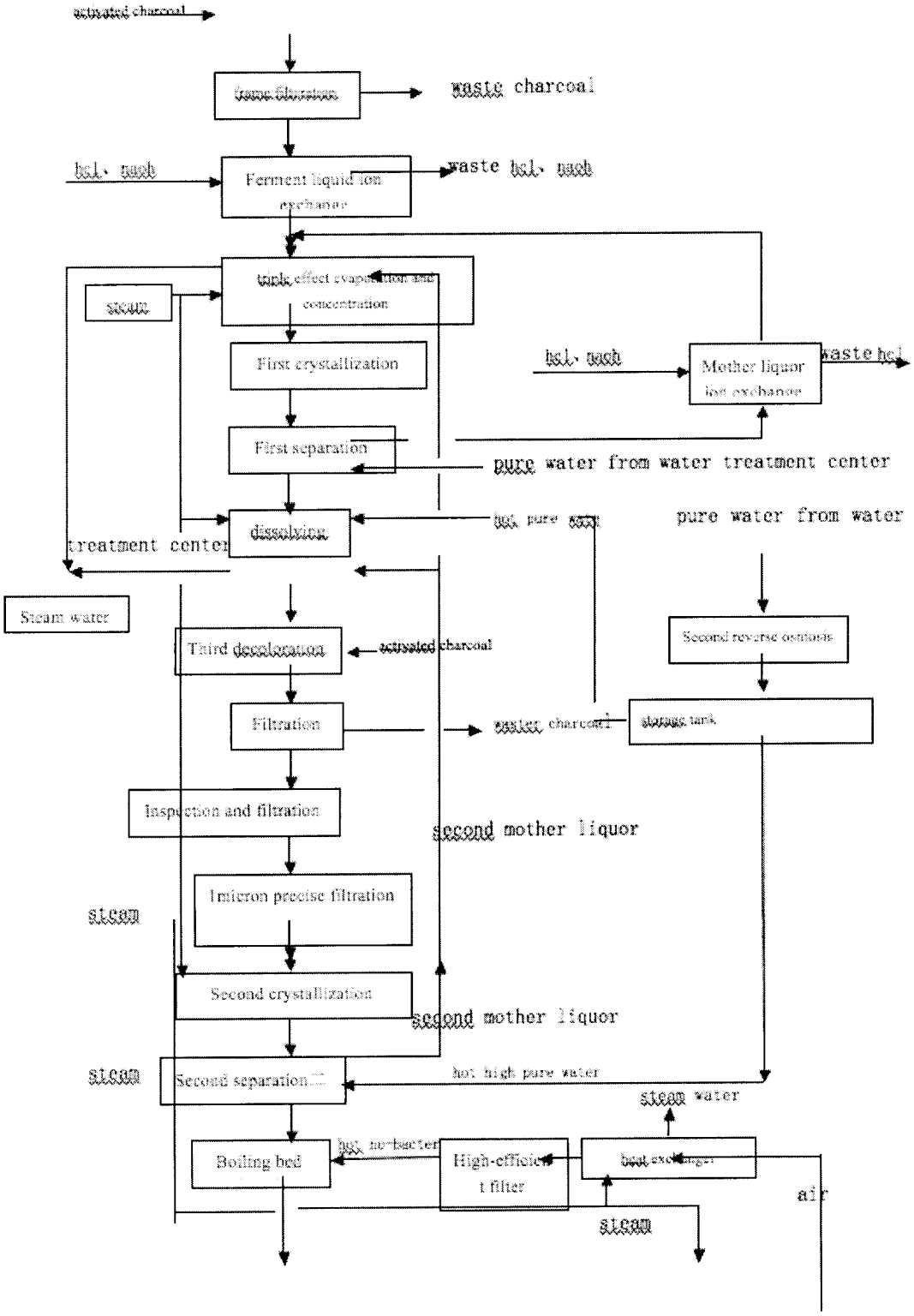
4.3.2.31 Sealing: 25kgs/bag finished products sealed by heat-sealing machine, operator inspect carefully if any air leak, then sew the package. Container bags sealed by tie ribbon and airproof by lead sealing lock

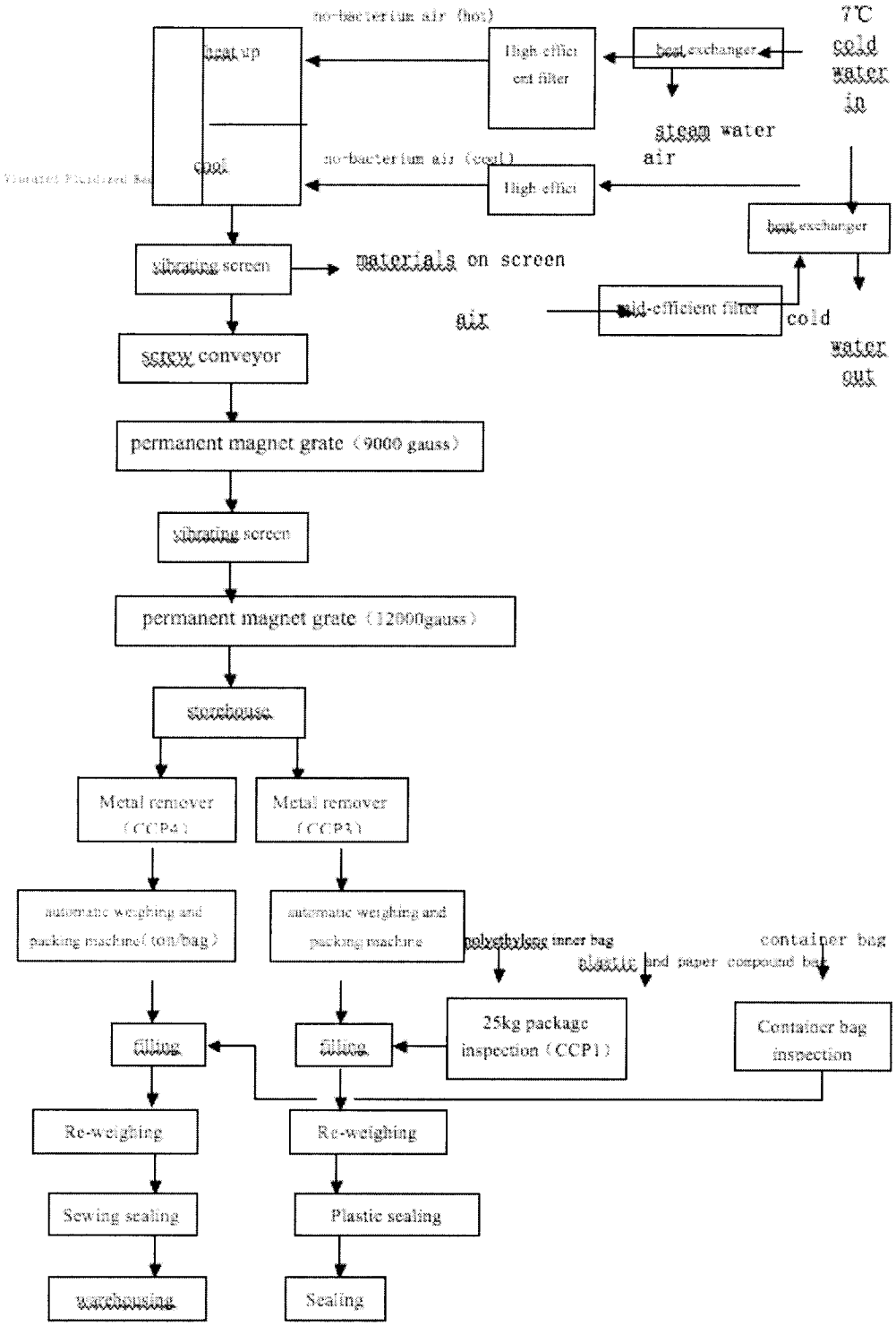
4.3.2.32 Warehousing: store the finished products to warehouse, labeling.

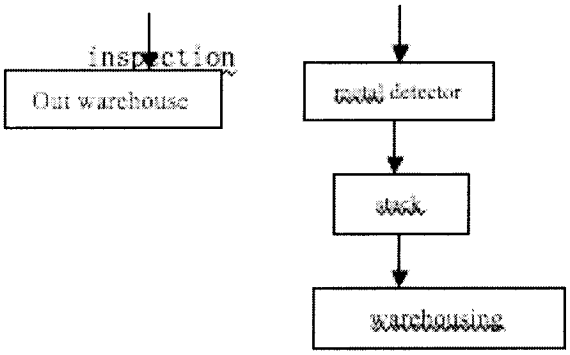
4.3.2.33 Out of warehouse: only after confirm the goods is eligible.

4.4 Summary Flow Chart for Manufacturing Process of Erythritol Produced by O'Laughlin Industries




activated charcoal
waste charcoal
waste hcl、nacl
Ferment liquid ion exchange
steam
First crystallization
hcl、nacl
Mother liquor
waste hcl
First separation
pure water from water treatment center
dissolution
pure water from water
treatment center
Steam water
Third decolorization
activated charcoal
Second reverse osmosis
Filtration
storage tank
Inspection and filtration
second mother liquor
1micron precise filtration
steam
Second crystallization
second mother liquor
steam
Second separation
hot high pure water
steam water
Boiling bed
High-efficient filter
air
steam


sterilization air (hot)
7℃
cold water in
heat up
High efficient filter
heat exchanger
steam water air
sterilization air (cool)
cool
High efficient
heat exchanger
vibrating screen
materials on screen
air
mid-efficient filter
cold water out
screw conveyor
permanent magnet grate (9000 gauss)
vibrating screen
permanent magnet grate (12000gauss)
storehouse
Metal remover (CCP4)
Metal remover (CCP3)
automatic weighing and packing machine(ton/bag)
automatic weighing and packing machine
polyethylene inner bag
container bag
plastic and paper compound bag
filling
filling
25kg package inspection (CCP1)
Container bag inspection
Re-weighing
Re-weighing
Sewing sealing
Plastic sealing
warehousing
Sealing


inspection
Out warehouse
metal detector
stock
warehousing

APPENDIX D

Methods Utilized for Analysis of Erythritol

1. Method for Determining the Melting Point of Erythritol

O'Laughlin (Tianjin) Industries Co., Ltd. Operations Standard----Operation Procedure for Test Standard						
Document Name	Test Standards for Melting Point			Code	SOP-QC-2010-00	
				Page	2-1	Date
Framer		Checker		Approver		
Date Prepared		Date Checked		Date Approved		
Preparing Dept	Quality Supervision	Distribution Dept	Quality Supervision Dep polyol team			

Purpose: determine the test operation standards for melting points
Application: Xylitol, somaltulose, Isomalt, Erythritol, etc
Responsibility: Analyst implement this operation, and lab leader supervise the implementation of the operation

Procedure
1. Principle
The melting point scope means the temperature scope measured by capillary tube method from incipient melting to melting completely.
By heating, increase the temperature from incipient melting points to final melting points, and then confirm the melting point scope.

2. Equipments :

2.1 Melting point tube: capillary tube made by neutral horniness glass, one side heat sealed, inside diameter 0.9-1.1mm, wall thickness 0.10-0.15mm, length higher than hot liquid after installed (about 100mm)
2.2 melting point apparatus: model YRT-3
2.3 **heat transfer fluid**: silicone oil

3、Operation steps:

3.1 Grinding the sample to fine powder, put into clean and dry melting point tube, put a dry glass tube erect on the glass board, put the melting point tube into the glass tube several times till the sample concentrated to 2-3mm height. If the samples are easy decomposing or dehydrated, another side of the melting point tube should be sealed.
3.2 Open the melting point apparatus, standby mode, press +,- key to set up the temperature lower 10℃ than samples' melting point in reset mode.

PS: the apparatus already remember the temperature, the preset temperature is same next time.
3.3 Press key "Ready" after preset temperature, "ready" light on, and the temperature increased by 15℃/min to the preset temperature. Around 1min after reaching preset temperature, the liquid on the stable temperature, buzzer warning, indicate it is already preset temperature, put the samples in
3.4 Put melting point tube that have sample into the hot liquid, the sample should close to the mid ceramics of platinum resistance thermometer as much as possible.
3.5 Press the key "test temperature", the sample is testing, and temperature increasing accordingly, operator observe the melting process by the magnifier.
3.6 Press "incipient melting", "final melting" key to record the data. In testing mode, press key "incipient melting", "final melting", the data will be remembered accordingly and relative lights on.

2. Method for Determining the Loss on Drying

O'Laughlin (Tianjin) Industries Co., Ltd. Work Standard----Quality test						
Document	Determination of loss on drying Standard operation			Code	SOP-QC-2008-00	
				Page	Page 1	Execute Date
Framer		Checker		Approver		
Date Prepared		Date Checked		Date Approved		
Preparing Dept.	Quality Supervision Dept.	Distribution Dept.	Quality Supervision Department			

Objective: To establish standard operating procedures Determination of loss on drying.

Scope: xylose, xylitol, erythritol, Isomaltulose alcohol.

Responsibilities: Quality Inspector does the operating procedures, and the laboratory director is responsible for overseeing the procedures correctly.

Procedure:

1, Brief

1.1 The dry weight loss drugs means drugs under specified conditions by weight loss after drying the percentage. Mainly refers to water, crystal water and other volatile substances, such as ethanol, from the weight loss and the sample size calculation of the dry weight loss of the test.

1.2 Loss on Drying method (Chinese Pharmacopoeia 2005 edition Appendix Ⅷ L) with oven drying, vacuum drying and the dryer temperature drying, which in turn sub-atmospheric pressure, vacuum two.

1.3 Oven drying method is suitable for heat stable drugs; temperature vacuum drying of water is more difficult for drug divisible; dryer drying method for drying the drugs can not be heated, vacuum evaporation of water can help.

2, Instruments and appliances

Flat weighing bottle, oven (maximum temperature of 300 ℃, temperature control accuracy of ± 1 ℃), temperature vacuum oven, dryer (ordinary) vacuum dryer, vacuum pump.

3, Reagent and the solution: commonly used desiccant dryer for the anhydrous calcium chloride, silica gel, phosphorus pentoxide or sulfuric acid (desiccant should remain in the active state.)

4, Steps

4.1 Weigh

Weigh 1g samples, and dry it under the same conditions to constant weight drying flat weighing bottle precision set.

4.2 Drying:

While drying, remove the cap, set beside the weighing bottle or the cap half open. Dried at 60 ℃ for 4 hours. Cover the caps when required to weigh good.

4.3 Weighing

4.3.1 Dry with a dryer for the test materials after drying out of the box said that given the weight.

4.3.2 Set oven or vacuum oven temperature for the test within the dry goods, should be set out in the dry and cool in the dryer

To room temperature (usually about 30 to 60 minutes), then said that given the weight.

4.4 constant weight, said after the test given by (4.2 ~ 4.3) to operate until a constant weight.

O'Laughlin (Tianjin) Industries Co., Ltd. Work Standard----Quality test			
Document	Determination of loss on drying Standard operation	Code	SOP - QC - 2008 - 00
		Page	Page 2

5 Notes

5.1 The provisions of the test without the dry humidity that melted, the test should be first in the low temperature drying to most of the water removed, then the provisions of the conditions dry.

5.2 When the temperature by vacuum dryer or vacuum oven, except as otherwise provided, the pressure should be 2.67kPa (20mmHg) below.

5.3 using the new vacuum dryer the first time are advised to use thick cloth outside, and then decompression.

5.4 Vacuum drying oven (for) openings, because box (device) is less than the external pressure, you must first unscrew the piston,

Let the dry air into the can lid. However, slowly unscrew the piston should be noted that in order to avoid air being blown towards the test.

5.5 Where the use of vacuum drying, should use single-layer glass cover weighing bottles. Such as hollow glass cover with double weighing bottles,

Decompression, the weighing bottle into the vacuum drying oven not (Utensils), the dryer should be placed inside another ordinary.

When the vacuum oven is under the temperature of 5.6, then the test site should be placed near the thermometer in order to avoid errors caused by uneven temperature inside.

5.7 Determination of loss on drying, often several at the same time the test, so weighing bottles are advised to use appropriate methods coded tags, bottle and cap encoding the same; the position of weighing bottle into the oven, remove the cooling load order, should have the same,

it is easier to obtain constant weight.

6, Recording and calculation

6.1 Record the temperature of drying, pressure, type of desiccant, dry and let cool to room temperature the time, weighing and

Constant weight data, calculations and results (as do those two parallel tests, the mean value) and so on.

6.2 Calculation

Loss on drying%= （(W1+W2-W3)/W1） *100%

W1 is the weight of the test (g);

weight W2 is the weight of weighing bottle (g);

W3 is (for the test materials weighing bottle +) constant weight weight (g).

7 Results found: The results of significant digits by rounding rules for rounding, the effective number of bits with the standard should be consistent with the provisions.

O'Laughlin （Tianjin） Industries Co., Ltd. Working Standard----Quality Test						
Filename	**The Determination Regulations for Colony Total Counts**			Coding	SOP-QC-7010-00	
				Page	3-1	Execute Date
Framer		Checker		Approver		
Date Prepared		Date Checked		Date Approved		
Preparing Dept.	Quality Supervision Dept.	Distribution Dept.	Quality Supervision Department			

Purpose : This regulates the determination method of colony total counts.

Application Scope : It applies to the determination of colony total counts in various foods.

Reference : GB/T 4789.2-2008 BAM, 8th ed Rev.A(1998),Chap.3

Procedure :

1 Instruments and Equipment

Besides the conventional sterilization and training instruments for microbiology lab the other equipment and materials are as the following.

1 Constant Temperature Incubator : 35℃±1℃。

2 Fridge : 0℃～5℃。

3 Constant Temperature Water Bath : 45℃±1℃。

4 Scale : The resolution (a Sense of Volume) is 0.1g.

5 Homogenizer.

6 Oscillator.

7 Sterile Pipette : 1mL(with0.01mL Calibration)、 10mL(with 0.1mL Calibration) or Transfer pipette and tip.

8 Sterile Flask : Capacity 250 mL、 500 mL。

9 Sterile Petri Dish : 90 mm diameter.

10 pH Meter

11 Magnifier or (and)Colony Counter

2 Culture Media and Reagents

1 PCA(Plate count agar)

2 Phosphate Buffer

3 Sterile Saline : Weigh 8. 5 g sodium chloride and dissolve it in 1000mL distilled water, sterilizing for 15 min with 121℃ high pressure.

4 1 mol／L Sodium Hydroxide(NaOH) : Weigh 40 g sodium hydroxide and dissolve it in 1000mL distilled water.

5 1 mol／L Hydrochloric Acid (HCl) : Take 90 mL HCl and dilute it with distilled water to 1000mL.

O'Laughlin (Tianjin) Industries Co., Ltd. Working Standard----Quality Test			
Filename	**The Determination Regulations for Colony Total Counts**	Coding	SOP-QC-7010-00
		Page	3-2

3 Operation Steps

4.1 Dilution of the sample

4.1.1 Solid and Semisolid Sample : Weigh 50g sample and put it in a sterile homogeneous cup that is containing 450mL phosphate buffer or sterile saline, homogenize for 1min--2min with 8000r/min--10000r/min, or put it in a sterile homogeneous bag that is containing 450mL diluents, and slap it for I min—2 min with slap-type Homogenizer (BagMixer) to make 1 : 10 homogeneous liquid sample.

4.1.2 Liquid Sample : Draw 50mL sample with sterile pipette and put it in a sterile flask that is containing 450mL phosphate buffer or sterile saline (preset appropriate number of sterile glass beads in the flask), mix well to make 1 : 10 homogeneous liquid sample.

4.1.3 Draw l0mL of 1 : 10 homogeneous liquid with 10mL sterile pipette or transfer pipette, and to fill it slowly into the sterile test tube that is containing 90mL diluents along its side(note that the pipette and its tip should not touch the diluents surface),shake the test tube or blow and slap it with a sterile pipette again and again to make it mixing well, so that to make 1: 100 homogeneous liquid sample.

4.1.4 Prepare ten-fold serial diluted homogeneous liquid sample according to the operation procedures indicated in 4.1.3. For increment dilution each time, 10mL sterile pipette or tip should be changed for use for each time.

4.1.5 Select 2 to 3 homogeneous liquid samples(the liquid samples may include the original liquid) that is with appropriate dilution according to the evaluation of the pollution status of the samples. Draw 1mL sample from each dilution and fill them into 3 sterile petri dishes respectively when carrying out the ten-fold increment dilution. Take 1mL dilution respectively at the same time and add them into 2 sterile petri dishes for blank control.

4.1.6 Pour 12mL--15mL PCA that has been cooled down to 45℃ in time (may put it in 45℃±1℃ constant temperature water wash for heat preservation) into the petri dish, and revolve the dish to make the PCA mixed well.

4.2 Culture

4.2.1 Overturn the plate after the solidation of agar, cultivate it for 48h±2 h at 35℃±1℃.

4.2.2 Cover with a think layer of culture medium of agar(about 4mL) on the surface of agar after solidation in case that the sample may contain the colony that grows and diffuses from the surface of agar culture medium. Overturn the plate after solidation for culture according to conditions under 4.2.1.

4.3 Colony Count

Observe by eyes, use magnifier or colony counter to record dilution fold and relevant colony amount if necessary. The colony count is indicated with colony-forming units(CFU).

4.3.1 Select colony count between 25 CFU and 250 CFU and total amount of plate count colony that the colony does not grow and diffuse. Record the specific colony count for the plate below 25CFU, May record as "many or uncountable" for that over 250 CFU. The average of 2 plates should be adopted for the colony count of each dilution.

O'Laughlin (Tianjin) Industries Co., Ltd. Working Standard----Quality Test			
Filename	**The Determination Regulations for Colony Total Counts**	Coding	SOP-QC-7010-00
		Page	3-3

4.3.2 It can not be adopted when there is a much more bigger platy colony growing in one of the plate, and the plate that there is no platy colony grows should be adopted as the colony count of dilution; if the platy colony does not reach half of the plate and the colony in the rest half distributes evenly it can represent a plate colony count after calculating the half plate, and multiply by 2.

4.3.3 When there is colony in chain shape grows on the plate, and there is no obvious boundaries between the colonies, then each single chain is taken as a colony count.

5 Result Description

5.1 Calculation Method of Colony Total Count

5.1.1 Calculate the average of colony count on 2 plates, then the average is multiplied by the corresponding dilution fold if there is only one dilution, and the colony count on the plate is within an appropriate range. It is taken as the colony total count n each gram(or mL).

5.1.2 If there are 2 serial dilutions and the colony count on the plate is within an appropriate range it is calculated according to formula (1) :

$$N = \sum C/(n_1 + 0.1n_2)d \quad \cdots\cdots\cdots (1)$$

N--the colony count in sample ;

∑C--sum of plate (it is containing appropriate range of colonies) colony count ;

n1--the colony count on the first plate with appropriate dilution ;

n2--the colony count on the second plate with appropriate dilution ;

d--dilution factor(first dilution).

5.1.3 If the colony count on all of the dilution plate is over 250 the highest dilution plate is counted, and as for the other plates it can be recorded as "many or uncountable", the result is calculated according to that the average colony count is multiplied by high dilution fold.

5.1.4 If the colony count on all of the dilution plate is below 25 it is calculated according to that the colony count of lowest dilution is multiplied by dilution fold.

5.1.5 If there is no colony grows on all the dilutions(including original liquid sample) plates, and then it is calculated by that the colony count less than 1 is multiplied by the lowest dilution fold.

5.1.6 If the colony count of all the dilution plates is not between 25 and 250 it is calculated that the average colony count that is most closest to 25 or 250 will be multiplied by dilution fold when most of them is less than 25 or more than 250.

5.2 Report on the colony total count

5.2.1 It will be rounded according to rules of rounding when the colony count is within 100. Two significant digits will be adopted for report.

5.2.2 More than or equal to 100, after the third digit is be rounded by rounding rules,take the first two digits, and use 0 to replace the digit behind it; also can use index of 10 to indicate, after it is rounded according to the rounding rules two significant digits are adopted.

5.2.3 It can not be counted if the colonies on all plates are the colonies that is diffusing, and then report the colony diffusing.

5.2.4 The test result will be invalid if there is colony that is growing on blank control.

5.2.5 For Weigh sampling the unit is reported as CFU/g, for volume sampling the unit is reported as CFU/mL.

3. Method for Determination of the Total Colony Count

4. Method for Determination of the Coliform Group Count

O'Laughlin (Tianjin) Industries Co., Ltd. Working Standard----Quality Test						
Filename	**The Determination Regulations for Coliform Group Count**			Coding	SOP-QC-7013-00	
				Page	2-1	Execute Date
Framer		Checker		Approver		
Date Prepared		Date Checked		Date Approved		
Preparing Dept.	Quality Supervision Dept.	Distribution Dept.		Quality Supervision Department		

Purpose : This standard regulates the determination method of coliform group count.

Application Scope : It applies to the determination of coliform group count in various foods.

Reference : GB/T 4789.3-2008 BAM, 8th ed Rev.A(1998),Chap.4

Procedure :

1 Instruments

Besides the conventional sterilization and training instruments for microbiology lab the other equipment and materials are as the following.

1 Constant Temperature Incubator : 35℃±1℃。

2 Fridge : 0℃～5℃。

3 Constant Temperature Water Bath : 45℃±1℃。

4 Scale : The resolution (a Sense of Volume) is 0.1g.

5 Homogenizer.

6 Oscillator.

7 Sterile Pipette : 1mL(with0.01mL Calibration)、 10mL(with 0.1mL Calibration) or Transferpette and tip.

8 Sterile Flask : Capacity 500 mL。

9 Sterile Petri Dish : 90 mm diameter.

10 pH Meter or pH Test Strips

11 Colony Counter

2 Culture Media and Reagents

1 Lauryl Sulfate Tryptose (LST) Broth

2 Brilliant Green Lactose Bile(BGLB) Broth

3 Phosphate Buffer

4 Sterile Saline : Weigh 8. 5 g sodium chloride and dissolve it in 1000mL distilled water, sterilizing for 15 min with 121℃ high pressure.

5 1 mol／L Sodium Hydroxide(NaOH) : Weigh 40 g sodium hydroxide and dissolve it in 1000mL distilled water.

5 1 mol／L Hydrochloric Acid (HCl) : Take 90 mL HCl and dilute it with distilled water to 1000mL.

O'Laughlin (Tianjin) Industries Co., Ltd. Working Standard----Quality Test			
Filename	**The Determination Regulations for Coliform Group Count**	Coding	SOP-QC-7013-00
		Page	2-2

3 Operation Steps

3.1 Dilution of the sample

3.1.1 Solid and Semisolid Sample : Weigh 50g sample and put it in a sterile homogeneous cup that is containing 450mL phosphate buffer or sterile saline, homogenize for 1min--2min with 8000r/min--10000r/min, or put it in a sterile homogeneous bag that is containing 450mL phosphate buffer or sterile saline, and slap it for lmin--2min with slap-type Homogenizer to make 1 : 10 homogeneous liquid sample.

3.1.2 Liquid Sample : Draw 50mL sample with sterile pipette and put it in a sterile flask that is containing 450mL phosphate buffer or sterile saline (preset appropriate number of sterile glass beads in the flask), shake fully to make 1 : 10 homogeneous liquid sample.

3.13 The pH value of the sample should be between 6.5 to 7.5.

3.1.4 Draw l0mL of 1 : 10 homogeneous liquid with 10mL sterile pipette or transferpette, and to fill it slowly into the

sterile test tube that is containing 90mL phosphate buffer or sterile saline along its side(note that the pipette and its tip should not touch the diluents surface),shake the test tube or instead blow and slap it with a 10ml sterile pipette again and again to make it mixing well, so that to make 1: 100 homogeneous liquid sample.

3.1.5 Based on the evaluation of the pollution status of the samples, and according to the above described operation to make ten-fold increment serial dilution of homogeneous liquid sample. For increment dilution each time, a 10mL sterile pipette or tip should be changed for use for each time. The time for the entire process from preparation of the homogeneous liquid sample to completion of sample inoculation should not be over 15 minutes.

3.2 Initial Fermentation Test

For each sample, select 3 appropriate homogeneous liquid samples of serial dilution (the original liquid may be selected as the liquid samples). For each dilution 3 tubes of LST broth is inoculated, 1ml for each tube(use twofold LST broth if the inoculation quantity is more than 1ml). Cultivate for 24h±2h at 35℃±1℃, observe that if there is gas bubble that generates in the tube,keep cultivating up to 48h±2h if there is no gas generation. Record the count of LST broth tubes that in which the gas generates within 24h and 48h. It is negative for coliform group if there is no gas generation. If there is gas generation then fermentation tests will be carried out again and again.

3.3 Re-Fermentation Test

Take 1 loop of culture with inoculation loop from all the tubes that containing LST broth and in which there is gas generation by fermentation within 48h±2h respectively, and transplant the culture in the BGLB broth tube to cultivate for 48h±2h at 35℃±1℃, observe the status of gas generation. It is positive for coliform group if there is gas generation.

3.4 Report on the MPN(most probable number) of Coliform Group

Based on the count of tubes that it positive for coliform group, and search the MPN table, report the MPN of coliform group per gram(or per ml) in the sample.

5. Method for Determination of Fungal Yeast

O'Laughlin (Tianjin) Industries Co., Ltd. Work Standard----Quality test						
Document	Inspection of molds and yeast count Standard operation			Code	SOP-QC-7011-00	
				Page	Page 1	Execute Date
Framer		Checker		Approver		
Date Prepared		Date Checked		Date Approved		
Preparing Dept.	Quality Supervision Dept.	Distribution Dept.	Quality Supervision Department			

Objective: This standard specifies the determination of fungal yeast count

Scope: This standard applies to all types of food in the determination of fungal yeast count

Brief : GB/T 4789.15 BAM, 8th ed Rev.A(1998),Chap.18

Procedure :

1 Instruments and materials

In addition to routine microbiological laboratory equipment, other equipment and materials as follows:

1 Incubator 25℃±1℃

2 Pressure sterilizer (Arnold sanitizer)

3 PH Meter

4 Water bath 45℃±1℃

2 Media and reagents

1 DRBC Agar

2 DG18 Agar

3 Plate count agar (PCA) standard method

4 Malt agar (MA)

5 Malt extract agar (molds and yeasts) (MEAYM)

6 Potato dextrose agar (PDA) Powder

Antibiotics adding method:

1.Recommended concentration of 100mg per liter of medium supplemented with chloramphenicol.

2.If the bacteria grow faster, then add 50mg per liter of culture medium after autoclave sterilized chloramphenicol and aureomycin 50mg filter.

1) Dissolved 0.1g Chloromycetinin into 40ml distilled water,and then add into 960ml medium before autoclaving

2)While use both chloramphenicol and chlortetracycline, take 20ml solution into 970ml sterile medium before the chloramphenicol,

dissolve 0.5g chlortetracycline into 100ml distilled water and then filter sterilized chlortetracycline,at last take 10ml solution into 990ml sterilized medium prepared.

O'Laughlin (Tianjin) Industries Co., Ltd. Work Standard----Quality test			
Docu ment	**Mold Yeast number inspection**	Code	SOP-QC-7011-00
		Page	Page 2

3 Procedure :

3.1 Prepare samples

3.1.1 Aseptically weigh 25-50ml samples, placed with 225-450ml of sterile 0.1% peptone water in conical flask with stopper, made of 10-1 dilution of homogenate in 2min

3.1.2 Diluted with sterile fluid into the pipette 10ml 10-1 with 90ml sterile 0.1% peptone water bottle with a tapered plug, homogenate after the 10-2 dilution.

3.1.3 Do the above sequence of operations increased 10-fold diluted solution can be diluted to 10-6,
based on estimates of pollution to the sample selection

3.2Plate and cultured

3.2.1 Coating method: Each sample dilution with a sterile pipette to draw 0.1ml pre-DRBC agar has solidified, and with the
Sterile bent glass rods inoculation, when the analysis of samples of water activity below 0.95, use DG18 agar, make three plates of each dilution sample.

3.2.2 Pour plate method: Draw with sterile pipette 1.0ml diluted in sterilized plate, and then immediately add 20-25ml DG18 agar in the plate and turn the plate and mix the sample solutions, and make three plates samples.

3.2.3 The samples were cultured at 25 ℃ in the dark.

4
Resu
lts

Start counting after 5days, if there is no growth colonies within five days, then cultured for another 48hrs,never count it again till it ends, take an average 10-150 plates colonies.

5 Report of Mold Yeast number

5.1 CFU/g as an unit of sample weight, CFU/mL as an unite of sample volume

5.2 Report results are based on the average of three repeated tests, into six four-round, five double-hash the principle of counting

5.3 When none of all the dilution plate colonies generated, the report molds and yeast count (MYC) is less than 1 times the minimum dilution factor calculation.

6. Method for Testing of Residual Sugar

<table>
<tr><td colspan="7">O'Laughlin (Tianjin) Industries Co., Ltd.
Operation Standard----Operation Procedure for Test Standard</td></tr>
<tr><td rowspan="2">Document</td><td colspan="3" rowspan="2">Residual Sugar (reducing sugar) Test Standard operation</td><td>Code</td><td colspan="2">SOP-QC-1006-00</td></tr>
<tr><td>Page</td><td>1-1</td><td>Date</td></tr>
<tr><td>Framer</td><td></td><td>Checker</td><td></td><td>Approver</td><td></td><td rowspan="2"></td></tr>
<tr><td>Date Prepared</td><td></td><td>Date Checked</td><td></td><td>Date Approved</td><td></td></tr>
<tr><td>Preparing Dept.</td><td>Quality Supervision Dept</td><td>Distribution Dept</td><td colspan="4">each laboratory</td></tr>
</table>

Purpose: determine the test procedures of residual sugar (reducing sugar), ensure residual sugar (reducing sugar) meets standards.

Application Scope: Xylitol, Isomalt, Erythritol, etc

References : "Food Additives Handbook " The third edition

Procedure

I. Apply to xylitol, erythritol finished products

1. Reagents: 0.5mg/ml glucose solution, Fehling's solution A & B (TS-80)

2. Equipment: two 10ml round bottom flasks

3、Steps :

3.1 Take 500mg sample into the 10ml round bottom flask, soluble in 2ml water

3.2 Add 2ml 0.5mg/ml glucose solution in another round bottom flask

3.3 Add 1ml each Fehling's solution A & B (TS-80) to the two round bottom flasks, heating up to boiling and then cooling.

3.4 Determination: if the turbidity of the sample is less then glucose solution, that is to say total sugar less than 0.2%

II. Apply to Isomalt, Erythritol

1、Reagents :

copper sulphate solution, take 0.4g copper sulphate ($CuSO_4 \cdot 5H_2O$) and dissolve in water to 100ml, blending completely.

Alkaline Tartrate solution, take 34.6g sodium potassium tartrate and 10g sodium hydroxide, dissolve in water to 100ml, put it two days and filter by glass wool

Ethanol, aether, etc.

2、Equipment: gooch funnel, 400mlbeaker, etc

3、Step: take 7g samples, put in the 400ml beaker, and add 35ml water, dissolving, blending. Add 25ml copper sulphate solution and 25ml Alkaline Tartrate solution, cover glass, heating to boiling in 4 min and keeping boiling for 2 min. put into the gooch funnel which cleaned by hot water, ethanol, aether and dry in 100℃ temperature for 30min, filter cuprous oxide, then put all the cuprous oxide on the filter cone, dry 30 min in 100℃ temperature, the weight of cuprous oxide should not more than 50mg

6. Test for Taste, Appearance and Odor of Erythritol

<table>
<tr><td colspan="7">O'Laughlin (Tianjin) Industries Co., Ltd.
Operation Standard----Operation Procedure for Test Standard</td></tr>
<tr><td rowspan="2">Documen t name</td><td colspan="3" rowspan="2">Test standard for Taste, appearance and Odor of Erythritol</td><td>Code</td><td colspan="2">SOP-QC-1012-00</td></tr>
<tr><td>Page</td><td>1-1</td><td>date</td></tr>
<tr><td>Framer</td><td></td><td>Checker</td><td></td><td>approver</td><td></td><td rowspan="2"></td></tr>
<tr><td>Date Prepared</td><td></td><td>Date Checked</td><td></td><td>D a t e Approve</td><td></td></tr>
<tr><td>Preparing Dept.</td><td>Quality Supervi sion Dept</td><td>Distributio n Dept</td><td colspan="4">Quality Supervision Dep lab.</td></tr>
</table>

Purpose: determine the test standards for taste, appearance and odor of erythritol, ensure the taste, appearance and odor of erythritol meet stipulated standards.
Application scope: Erythritol
Reference: customer's standards

Procedure:
1. Equipments
1.1 electronic analytical balance, sensible weight 0.0001g
1.2 mini blender
1.3 de-ionized water or distilled water
1.4 two 1000ml volumetric flasks

1.5 Magnetic blender
2 Control/preparing samples/ dilution
2.1 Analysis step: control concentration/sample: 10g/l, take 10g samples in tared dish and flask, put into 1000ml volumetric flask, dilution to scale, test by eye survey, smell and taste.

	Typical Specification		Typical defect	
	Integrity/non-dilution	Dilution	Integrity/non-dilution	Dilution
Appearance	white crystal, good liquidity	colorless, clear, not turbidity	granule, agglomeration, bad color	turbidity、bad color
Odor	no taste		have ferment odor, sulfur odor, green color, old odor	have ferment odor, sulfur odor, green color, old odor
Taste	sweet, cooling	sweet, cooling	have ferment odor, sulfur odor, green color, old odor	have ferment odor, sulfur odor, green color, old odor

7. Test Standard Operation for pH

O'Laughlin (Tianjin) Industries Co., Ltd. Operation Standard----Operation Procedure for Test Standard						
Document Name	Test standard for PH			Code	SOP-QC-2016-00	
				Page	1-1	Date
Framer		Checker		Approver		
Date Prepared		Date Checked		Date Approved		
Preparing Dept.	Quality Supervision Dept	Distribution Dept	Quality Supervision Dep polyol team, plant lab.			

Purpose: determine the test standard operation for PH
Application: Xylose, Xylitol, water

Procedure
Equipment: PH Meter, 50ml beaker, electric cooker, thermometer

2、Emendation Equipment:

According to "Test standard for PH" SOP-QC-6007-00 emendation PH meter

3. Operation Steps:

Take 20g sample (water or water solution could test directly, but doesn't go through electrode pole) into 50ml beaker, and add 20ml boiled but room temperature water, adjust temperature and PH meter to 25℃±1℃, test the PH data.

(PS: use water first, and sample solution wash electrode pole several times, re-test, and the measured data can't exceed 0.05PH)

4、Reading

PH data stable within 1 min, reading

5、Results report

Take the arithmetic mean value of the two times reading as the report result.

APPENDIX E-1

HPLC Analysis of Erythritol in Five Commercial Lots

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O'Laughlin (TianJin) Industries Co.,Ltd.

HPLC Assay of Erythritolin in Five commercial lots

Prepared by:_____ **Date :** _____

Approved by:_____ **Date :** _____

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O'Laughlin(TianJin)Industries Co.,Ltd.

Objective

To determine related Erythritol content in five commercial lots of Erythritol produced by O'Laughlin (TianJin) Industries Co.,Ltd.

Samples

Five samples representing commercial lots of Erythritol labeled as "20101102-1", "20101124-1", "20101126-1", "20101204-3", and "20110103-3".

Standards

1 . Erythritol Standard; Lot#13666 (Crystal Pure Reagent Co., Ltd. Shanghai)

2 . Ribitol Standard; Lot#A0275980 (New Jersey , USA)

3 . Glycerol Standard;Lot#15069 (Tianjin Trade Xuan Angke)

Solvents and Reagents

Mobile Phase Use twice-distilled water.

Apparatus

1.Agilent 1200 HPLC system equipped with binary pump (G1312B), auto sampler(GI367D), thermostatted column compartment (G1316B) and refractive index detector, (Agilent Technologies, USA);

2 . Chromatographic System. Use a high-performance liquid chromatograph equipped with a constant-flow, pulseless pump and fitted with a sensitive differential refractive index detector. The column is packed with a strong cation exchange resin in the hydrogen form consisting of a macroreticular sulfonated polystyrene.

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divinylbenzene and an 8% crosslinked copolymer, Shodex SH1011(Showa Denko, Ltd.). The flow rate is about 0.6 mL/min, and the maximum pressure of the system is about 1500 psi.

3 . Analytical balance, FA2004N , (CANY , ShangHai China) .

4. Volumetric (class A) and Laboratory glassware.

Solution preparation

Mobile Phase, and Diluent were prepared as per FCCV monograph method (see appendix A).

Standard solutions

Standard preparation: Transfer 500 mg of Erythritol Standard1 and 50 mg each of reagent-grade Glycerol and Ribitol, accurately weighed, into a 100mL volumetric flask. Dilute to volume with Mobile Phase, and mix. Save this preparation for the Ribitol and Glycerol Test.

Sample solution

Assay Preparation: Transfer 4.0g of sample, accurately weighed, into a 25mL volumetric flask. Add Mobile Phase to volume, and mix. Filter through a 0.45μm filter before injecting into the chromatograph. Save this preparation for the Ribitol and Glycerol Test.

Chromatonraphic system

1 . Chromatograph-Agilent 1200 series HPLC equipped with binary pump, autosampler, thermostatted column compartment and a sensitive differential refractive index detector.

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2 . The column is packed with a strong cation exchange resin in the hydrogen form consisting of a macroreticular sulfonated polystyrene divinylbenzene and an 8% crosslinked copolymer, Particle size 5μm, as Shodex SH1011 (Showa Denko, Ltd.).

3. The flow rate is about 0.6mL/min, and the maximum pressure of the system is about 1500 psi ;

4. Column temperature 60℃.

5. Injection volume 10 μL.

System Suitability Requirements (see appendix B);

System suitability was checked as per FCCV monograph method.

Analysis

Analysis and calculations were performed as per FCCV monograph method for Erythritol and Glycerol, and Ribitol (see appendix A).

The assay results are summarized in Table 1.

Table 1

Erythritol and Glycerol, and Ribitol assay

Lot#	Erythritol and Glycerol, and Ribitol assay,% Dry bassis			
	Glycerol	Ribitol	Glycerol and Ribitol Total	Erythritol
20101102-1	ND	ND	ND	99.8826
20101124-1	0.0149	0.0107	0.0256	99.8728
20101126-1	ND	0.0120	0.0120	99.8872
20101204-3	0.0123	0.0135	0.0258	99.8936
20110103-3	ND	ND	ND	99.8897

ND -Not Detected

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Reference

1. Erythritol monograph Food Chemicals Codex (FCC) -149-32-6.
2. Procedure

Mobile Phase: Use twice-distilled water.

Diluent: Use twice-distilled water.

Standard Preparation: Transfer 500 mg of Erythritol Standard1 and 50 mg each of reagent-grade Glycerol and Ribitol, accurately weighed, into a 100mL volumetric flask. Dilute to volume with Mobile Phase, and mix. Save this preparation for the Ribitol and Glycerol Test.

Sample solution: Transfer 4.0 g of sample, accurately weighed, into a 25-mL volumetric flask. Add Mobile Phase to volume, and mix. Filter through a 0.45μm filter before injecting into the chromatograph. Save this preparation for the Ribitol and Glycerol Test.

Mode: High-performance liquid chromatography

Detector: Differential refractive index detector.

Column: The column is packed with a strong cation exchange resin in the hydrogen form consisting of a macroreticular sulfonated polystyrene divinylbenzene and an 8% crosslinked copolymer, Particle size 5μm, Shodex SH1011 (Showa Denko, Ltd.).

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Column temperature: 60℃.

Flow rate: 0.6mL/min, and the maximum pressure of the system is about 1500 psi.

Injection sire: 10μL.

System suitability

Samples: 500 mg /100ml Erythritol Standard1and 50 mg/100ml Glycerol and Ribitol sample solution.

Suitability requirements

Detector response:

Procedure Separately inject equal volumes of about 10μL each of the Standard Preparation, followed by the Assay Preparation, into the chromatograph, and record the peak responses over a period of 60 min. The relative retention times are 1.0 for Erythritol, 1.1 for Glycerol, and 0.9 for Ribitol. Calculate the percentage of Erythritol in the sample taken by the equation

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APPENDIX A

Erythritol, Assay Monographs / Erythritol / 153

Analysis: Separately inject equal volumes of the Erythritol standard solutions, Glycerol, and Ribitol standard solutions, and Sample solution into the chromatograph, and measure the responses for the major peaks on the resulting chromatograms.

Chromatographic Profile Table1

Compound	Approx Retention Time(min)	Molecular Weight(g/mol)
Ribitol	9.8	152.15
Erythritol	10.6	122.12
Glycerol	11.7	92.09

Prepare a standard curve for Erythritol by plotting Erythritol peak areas versus concentrations in mg/L, corrected for purity, based on the USP Reference Standard label claim.

From the standard curve, calculate the concentration (CU) of Erythritol in the Sample solution in mg/L Calculate the percentage of Erythritol in the portion of the sample taken by the formula:

$$Cu/Cmsp \times 100\%$$

Cu=Concentration of Erythritol in the Sample solution determined from the standard curve (mg/L)

Cmsp= Concentration of the sample in the Sample solution

Related Erythritol

Mobile phase, Diluent, Erythritol standard solutions,

Erythritol standard stock solution, Erythritol standard solutions, sample solution, Chromatographic system, and System suitability: Prepare as directed in the Assay (above).

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APPENDIX A

Analysis: Proceed as directed above in the Assay, but with the following modifications for the standard curve and calculations.

Using the peak area responses from the Erythritol standard solutions, prepare a standard curve for Erythritol by plotting Erythritol peak areas versus concentrations, in mg/L, corrected for purity, based on the USP Reference Standard label claim. From this standard curve, determine the concentration (mg/l) of Erythritol in the Sample solution. Calculate the percent of Erythritol in the sample taken using the following formula

$$Cu/Cmsp \times 100\%$$

Cu=Concentration of Erythritol in the Sample solution determined from the standard curve (mg/L)

Cmsp= Concentration of the sample in the Sample solution

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Appendix B

System Suitability Check

B1 Detector response

B2 % Relative standard deviation of Erythritol peak area and retention time

B3 Column efficiency and tailing factor

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Appendix B1

1 . Detect or response

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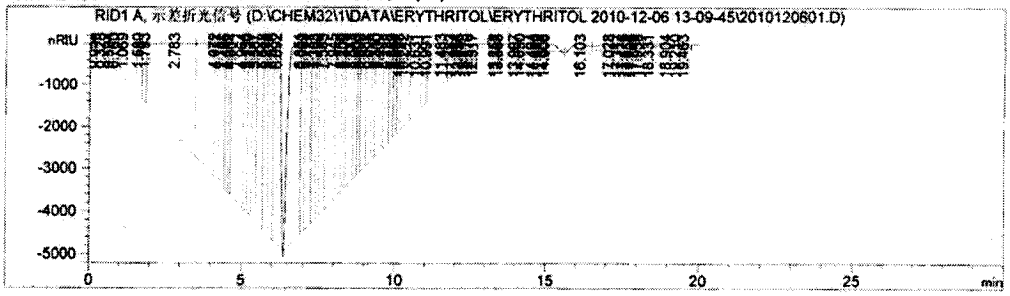

面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

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1	0.054	BV	0.1607	532.74707	43.35028	0.0280
2	0.328	VV	0.2136	4497.99609	256.01840	0.2362
3	0.594	VV	0.1029	3938.65381	466.31561	0.2068
4	0.760	VV	0.2655	1.33328e4	595.58063	0.7000
5	1.069	VV	0.4760	3.34379e4	834.71063	1.7556
6	1.580	VV	0.1400	1.42472e4	1224.67493	0.7480
7	1.793	VV	0.1004	1.14374e4	1388.35437	0.6005
8	2.783	VV	1.0840	2.01406e5	2180.70410	10.5745
9	4.072	VV	0.4268	1.14568e5	3180.27148	6.0152
10	4.187	VV	0.1181	3.19001e4	3270.12646	1.6749
11	4.406	VV	0.1261	3.46166e4	3439.69312	1.8175
12	4.511	VV	0.0799	2.27956e4	3520.85205	1.1968
13	4.604	VV	0.0572	1.62805e4	3593.50073	0.8548
14	4.964	VV	0.2943	9.56402e4	3876.87939	5.0214
15	5.130	VV	0.1018	3.19767e4	4005.60205	1.6789
16	5.227	VV	0.1340	3.27959e4	4080.29736	1.7219
17	5.387	VV	0.1143	3.73029e4	4203.96436	1.9585
18	5.648	VV	0.1631	5.83385e4	4406.97461	3.0630
19	5.774	VV	0.1221	4.38016e4	4505.38379	2.2997
20	5.936	VV	0.1268	4.60338e4	4630.62939	2.4169
21	6.092	VV	0.1968	7.66232e4	4751.70605	4.0230
22	6.851	VV	0.3237	1.23544e5	4607.05664	6.4864
23	6.959	VV	0.1102	4.02107e4	4524.55420	2.1112

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		进样量	: 10 µl
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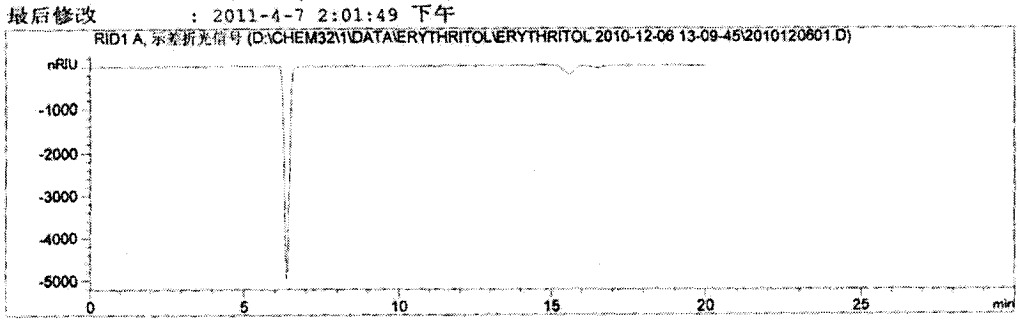

面积百分比报告

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稀释因子	:	1.0000

内标使用乘积因子和稀释因子

未发现峰

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质监部

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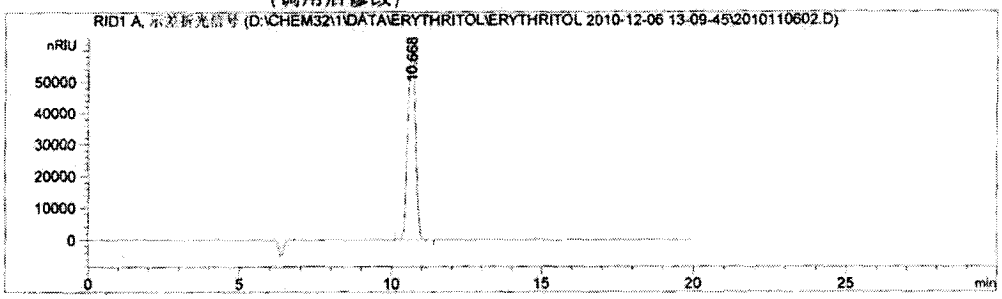
样品名称: cxiantchun

操作者	:	序列行	: 2
仪器	: 仪器 1	位置	: 样品瓶 3
进样日期	: 2010-12-6 1:32:52 下午	进样次数	: 1
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-06 13-09-45\ERYTHRITOL.M		
最后修改	: 2011-4-7 10:59:04 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-06 13-09-45\2010110602.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2011-4-7 2:02:05 下午 (调用后修改)		



面积百分比报告

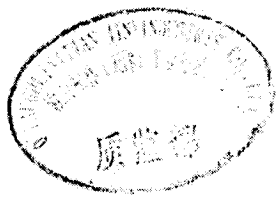
排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

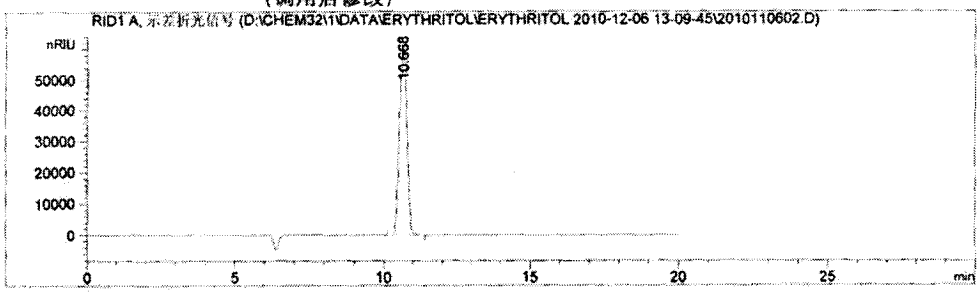
峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	10.668	BBA	0.2949	1.10084e6	6.09630e4	100.0000
总量 :				1.10084e6	6.09630e4	

*** 报告结束 ***



数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-06 13-09-45\2010110602.D
样品名称: cxiantchun

操作者	:	序列行 :	2
仪器	: 仪器 1	位置 :	样品瓶 3
进样日期	: 2010-12-6 1:32:52 下午	进样次数 :	1
		进样量 :	10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-06 13-09-45\ERYTHRITOL.M		
最后修改	: 2011-4-7 10:59:04 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-06 13-09-45\2010110602.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2011-4-7 2:02:05 下午 (调用后修改)		



面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	10.668	BBA	0.2949	1.10084e6	6.09630e4	100.0000
总量 :				1.10084e6	6.09630e4	

*** 报告结束 ***

仪器 1 2011-4-7 2:02:07 下午 页 1/1

O'LAUGHLIN

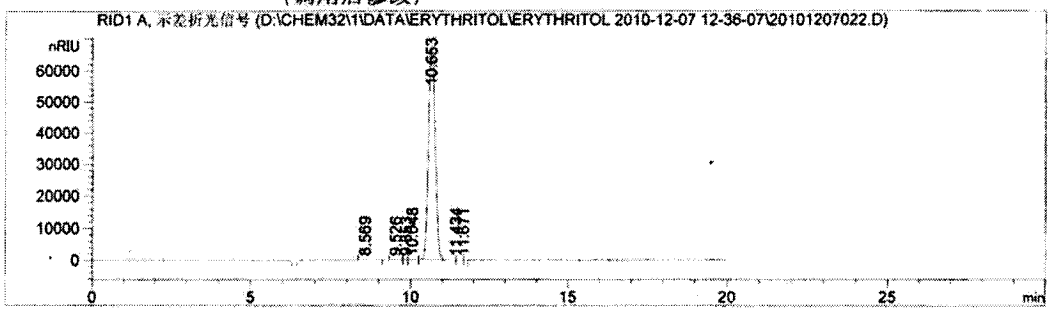
O'Laughlin (TianJin) Industries Co.,Ltd.

APPENDIX B2

2. %RSD of **Erythrol peak** area and retention time

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\20101207022.D
样品名称: 20101102-1

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 2
进样日期	: 2010-12-7 12:59:02 下午	进样次数	: 2
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\ERYTHRITOL.M		
最后修改	: 2010-12-7 11:00:55 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\20101207022.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-11-22 10:20:00 上午 (调用后修改)		



面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

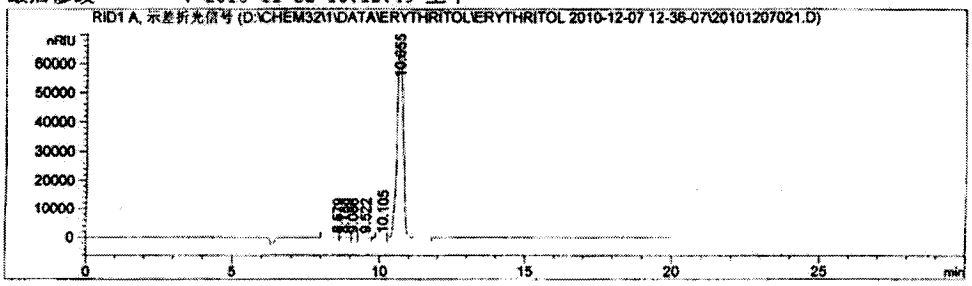
峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	8.569	VV	0.3553	501.53134	17.31250	0.0506
2	9.526	VV	0.2080	130.00743	7.61000	0.0131
3	9.853	VV	0.0984	32.10489	4.27750	3.239e-3
4	10.048	VV	0.1982	137.58890	8.97750	0.0139
5	10.653	VF	0.2327	9.89996e5	6.70777e4	99.8749
6	11.434	VF	0.2047	318.18527	25.91000	0.0321
7	11.671	VBA	0.1181	121.00320	17.07000	0.0122
总量 :				9.91236e5	6.71589e4	

*** 报告结束 ***

质监部

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\20101207021.D
样品名称: 20101102-1

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 2
进样日期	: 2010-12-7 12:37:27 下午	进样次数	: 1
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\ERYTHRITOL.M		
最后修改	: 2010-12-7 11:00:55 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\20101207021.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-11-22 10:12:49 上午		



面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

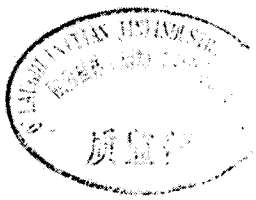
信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	8.579	BV	0.2231	212.19554	11.54583	0.0214
2	8.788	VV	0.2654	311.37988	13.91551	0.0315
3	9.086	VV	0.1483	124.55923	10.73450	0.0126
4	9.522	VV	0.2779	298.73166	13.15422	0.0302
5	10.105	VV	0.2383	215.43182	11.26290	0.0218
6	10.655	VV	0.2348	9.88727e5	6.69993e4	99.8826
总量 :				9.89889e5	6.70600e4	

*** 报告结束 ***

相对标准偏差.
面积 = 0.091%
时间 = 0.013%

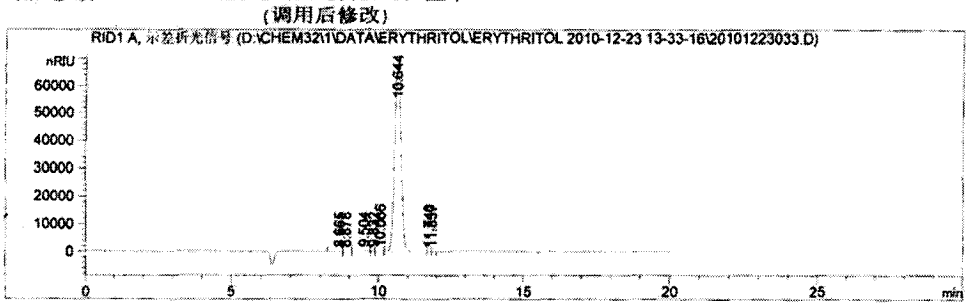
$X = 100 \times E / T$
$= 100 \times 988727 / 989889 = 99.88\%$



仪器 1 2010-11-22 10:21:20 上午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\20101223033.D
样品名称: 20101124-1

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 3
进样日期	: 2010-12-23 2:18:18 下午	进样次数	: 3
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\ERYTHRITOL.M		
最后修改	: 2010-12-23 10:56:32 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\20101223033.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-11-22 10:24:39 上午 (调用后修改)		



面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	8.665	VV	0.2952	246.84079	9.97542	0.0235
2	8.878	VV	0.2004	156.20390	9.83667	0.0149
3	9.504	VV	0.3213	353.12103	13.17667	0.0336
4	9.832	VV	0.1255	96.77934	9.66417	9.221e-3
5	10.066	VV	0.1997	204.68205	12.49667	0.0195
6	10.644	VV	0.2450	1.04826e6	6.78819e4	99.8771
7	11.740	VF	0.1190	130.80519	13.56542	0.0125
8	11.837	VV	0.1427	101.71192	11.87667	9.691e-3
总量 :				1.04955e6	6.79625e4	

*** 报告结束 ***

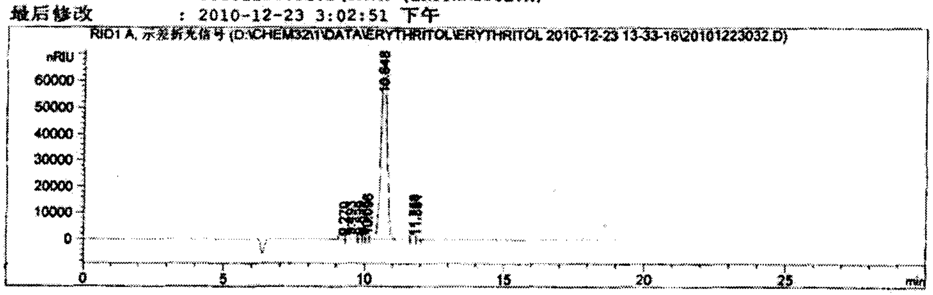
质控部

仪器 1 2010-11-22 10:24:42 上午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\20101223032.D
样品名称: 20101124-1

操作者	:	序列行 :	1
仪器	: 仪器 1	位置 :	样品瓶 3
进样日期	: 2010-12-23 1:56:43 下午	进样次数 :	2
		进样量 :	10 µl

采集方法 : D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\ERYTHRITOL.M
最后修改 : 2010-12-23 10:56:32 上午
分析方法 : D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\20101223032.D\DA.M (ERYTHRITOL.M)
最后修改 : 2010-12-23 3:02:51 下午



面积百分比报告

排序 : 信号
乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	9.270	VV	0.1616	165.57886	12.99750	0.0158
2	9.493	VV	0.2957	409.47308	16.39750	0.0390
3	9.839	VV	0.0975	112.24400	14.04750	0.0107
4	9.973	VV	0.0886	110.78896	15.34250	0.0106
5	10.096	VV	0.1018	126.87678	15.53322	0.0121
6	10.648	VV	0.2471	1.04753e6	6.78295e4	99.8728
7	11.758	VF	0.1583	252.76239	19.43000	0.0241
8	11.851	VV	0.1454	156.50752	17.94000	0.0149
总量 :				1.04886e6	6.79412e4	

质监部

*** 报告结束 ***

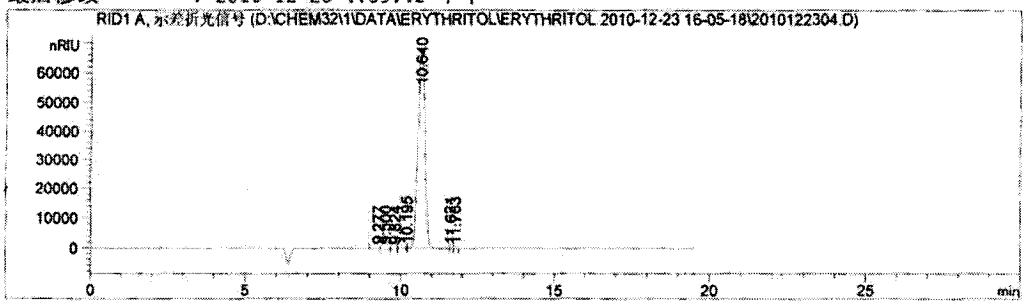
相对标准偏差
面积: 0.509
时间: 0.027

X= 100×E/F = 100× 1047530/1048860 = 99.87%
核糖= 100×E/F = 100× 112/1048860 = 0.0106%
甘露 = 100×E/F = 100× 158/1048860 = 0.0149%

仪器 1 2010-11-22 10:23:04 上午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 16-05-18\2010122304.D
样品名称: 20101126-1

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 4
进样日期	: 2010-12-23 4:07:13 下午	进样次数	: 1
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 16-05-18\ERYTHRITOL.M		
最后修改	: 2010-12-23 10:56:32 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 16-05-18\2010122304.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-12-23 4:39:42 下午		



面积百分比报告

排序 : 信号
乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	9.277	VV	0.2066	138.18439	8.41750	0.0131
2	9.500	VV	0.2016	179.87669	10.63750	0.0170
3	9.824	VV	0.1581	126.95391	9.90750	0.0120
4	10.195	VV	0.1608	309.12796	32.04000	0.0293
5	10.640	VV	0.2471	1.05482e6	6.82963e4	99.8872
6	11.621	VV	0.0996	202.90878	25.42000	0.0192
7	11.783	VV	0.1203	234.03438	24.44625	0.0222
总量 :				1.05601e6	6.84072e4	

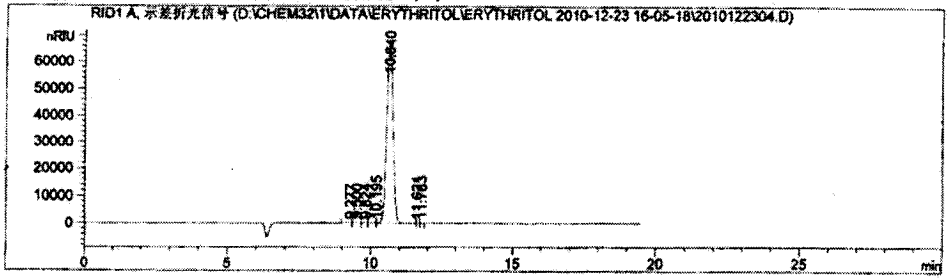
*** 报告结束 ***

质监部

仪器 1 2010-11-22 10:26:46 上午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 16-05-18\2010122304.D
样品名称: 20101126-1

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 4
进样日期	: 2010-12-23 4:07:13 下午	进样次数	: 1
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 16-05-18\ERYTHRITOL.M		
最后修改	: 2010-12-23 10:56:32 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 16-05-18\2010122304.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-12-23 4:39:42 下午		



面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	9.277	VV	0.2066	138.18439	8.41750	0.0131
2	9.500	VV	0.2016	179.87669	10.63750	0.0170
3	9.824	VV	0.1581	126.95391	9.90750	0.0120
4	10.195	VV	0.1608	309.12796	32.04000	0.0293
5	10.640	VV	0.2471	1.05482e6	6.82963e4	99.8872
6	11.621	VV	0.0996	202.90878	25.42000	0.0192
7	11.783	VV	0.1203	234.03438	24.44625	0.0222
总量 :				1.05601e6	6.84072e4	

*** 报告结束 ***

质监部

相对标准偏差
面积: w5
w10 : 0.18

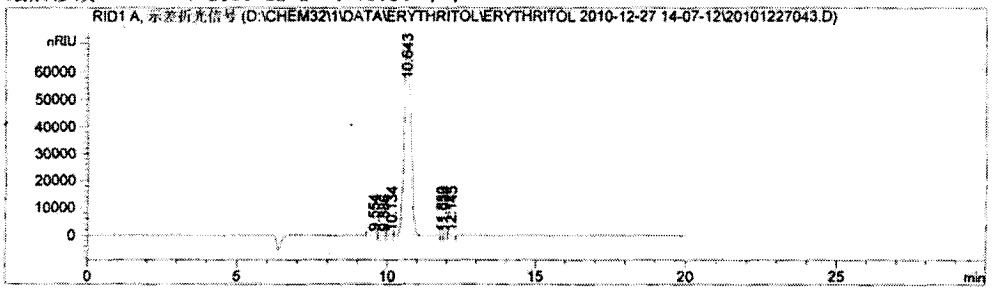
X=100/1 = 100 × 1.05482e6/1.05601e6 = 99.88 %

X杂 = 100/1 = 100 × 126/105601e6 = 0.0119

仪器 1 2010-11-22 10:26:46 上午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\20101227043.D
样品名称: 20101204-3

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 4
进样日期	: 2010-12-27 2:52:22 下午	进样次数	: 3
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\ERYTHRITOL.M		
最后修改	: 2010-12-27 11:29:10 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\20101227043.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-12-27 4:15:36 下午		



面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	9.554	VV	0.2393	219.67119	11.01000	0.0201
2	9.886	VV	0.1844	148.03516	9.59000	0.0135
3	10.134	VV	0.1633	168.45750	12.88625	0.0154
4	10.643	VV	0.2491	1.09210e6	6.99396e4	99.8936
5	11.830	VV	0.0834	133.95280	20.91000	0.0123
6	11.934	VV	0.0987	149.05566	20.79750	0.0136
7	12.145	VV	0.1988	343.89117	21.34250	0.0315
总量 :				1.09327e6	7.00362e4	

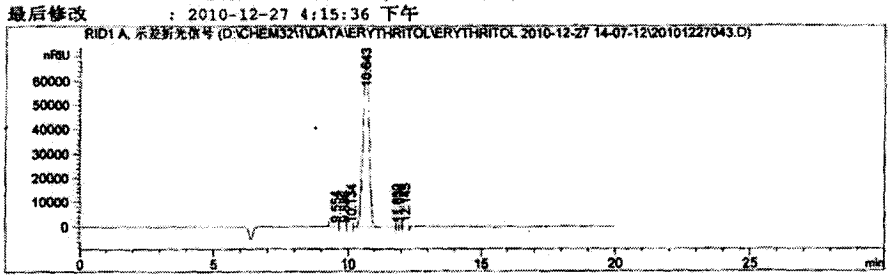
*** 报告结束 ***

质监部

仪器 1 2010-11-22 10:29:03 上午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\20101227043.D
样品名称: 20101204-3

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 4
进样日期	: 2010-12-27 2:52:22 下午	进样次数	: 3
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\ERYTHRITOL.M		
最后修改	: 2010-12-27 11:29:10 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\20101227043.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-12-27 4:15:36 下午		



面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	9.554	VV	0.2393	219.67119	11.01000	0.0201
2	9.886	VV	0.1844	148.03516	9.59000	0.0135
3	10.134	VV	0.1633	168.45750	12.88625	0.0154
4	10.643	VV	0.2491	1.09210e6	6.99396e4	99.8936
5	11.830	VV	0.0834	133.95280	20.91000	0.0123
6	11.934	VV	0.0987	149.05566	20.79750	0.0136
7	12.145	VV	0.1988	343.89117	21.34250	0.0315
总量 :				1.09327e6	7.00362e4	

质监部

*** 报告结束 ***

相对标准偏差
面积 = 0.11%
时间 = 0.%

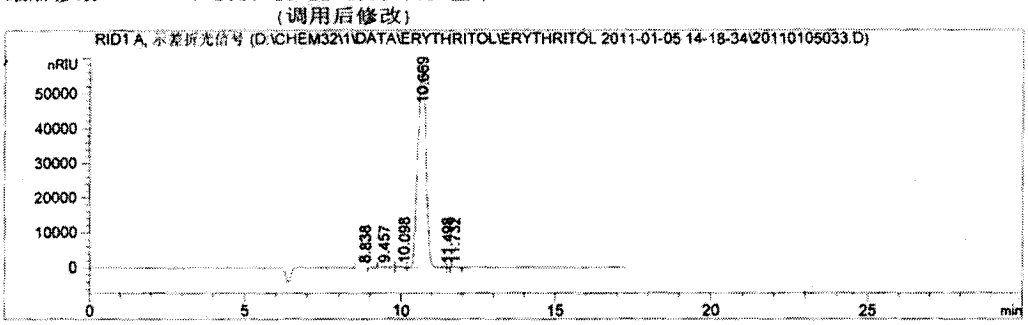
X=100%/T = 100×1092100/1093270 = 99.89%

方差 = 100%/T = 100×1358/1093270 = 0.0125
方差 = 100%/T = 100×133/1093270 = 0.0122

仪器 1 2010-11-22 10:29:03 上午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-01-05 14-18-34\20110105033.D
样品名称: 20110103-3

操作者 :　　序列行 : 1
位置 : 样品瓶 3
进样日期 : 05-Jan-11, 15:03:20　　进样次数 : 3
采集方法 : ERYTHRITOL.M
分析方法 : D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-01-05 14-18-34\20110105032.D\DA.M (ERYTHRITOL.M)
最后修改 : 2010-11-22 10:36:43 上午
(调用后修改)



面积百分比报告

排序 : 信号
乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	8.838	BV	0.1900	120.31622	7.83514	0.0114
2	9.457	VV	0.2856	280.41962	11.72300	0.0265
3	10.098	VV	0.2429	212.34584	10.57708	0.0200
4	10.669	VV	0.3017	1.05866e6	5.73672e4	99.8897
5	11.498	VB	0.1071	137.16292	21.34818	0.0129
6	11.732	BBA	0.2290	418.54865	22.16347	0.0395
总量 :				1.05983e6	5.74409e4	

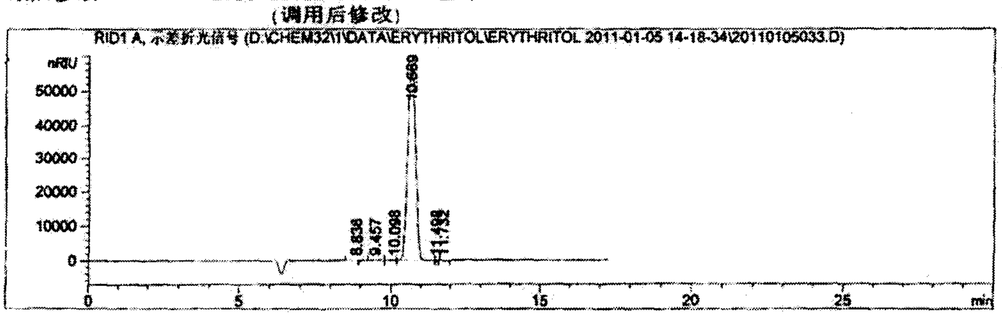
*** 报告结束 ***

质监部

仪器 1 2010-11-22 10:36:46 上午　　页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-01-05 14-18-34\20110105033.D
样品名称: 20110103-3

操作者 :　　　　　　　　　　　　　序列行 : 1
位置 : 样品瓶 3
进样日期 : 05-Jan-11, 15:03:20　　　　进样次数 : 3
采集方法 : ERYTHRITOL.M
分析方法 : D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-01-05 14-18-34\20110105032.D\DA.M (ERYTHRITOL.M)
最后修改 : 2010-11-22 10:36:43 上午
(调用后修改)



面积百分比报告

排序 : 信号
乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	8.838	BV	0.1900	120.31622	7.83514	0.0114
2	9.457	VV	0.2856	280.41962	11.72300	0.0265
3	10.098	VV	0.2429	212.34584	10.57708	0.0200
4	10.669	VV	0.3017	1.05866e6	5.73672e4	99.8897
5	11.498	VB	0.1071	137.16292	21.34818	0.0129
6	11.732	BBA	0.2290	418.54865	22.16347	0.0395

总量 : 1.05983e6 5.74409e4

*** 报告结束 ***

相对标准偏差
面积=0.7?
时间=0.033

本 10E/个 = 100x 1058669/1059830 = 99.89%

仪器 1 2010-11-22 10:36:46 上午　　　　页 1/1

O'LAUGHLIN

O'Laughlin(TianJin)Industries Co.,Ltd.

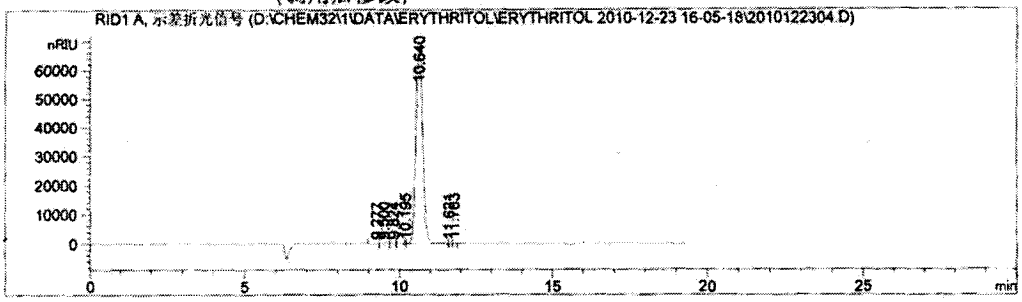
APPENDIX B3

3. Column efficiency and tailing factor

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 16-05-18\2010122304.D
样品名称: 20101126-1

检验报告

操作者	:	序列行 :	1
仪器	: 仪器 1	位置 :	样品瓶 4
进样日期	: 2010-12-23 4:07:13 下午	进样次数 :	1
		进样量 :	10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 16-05-18\ERYTHRITOL.M		
最后修改	: 2010-12-23 10:56:32 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 16-05-18\2010122304.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-12-23 4:18:47 下午 (调用后修改)		



面积百分比报告(包含性能计算)

乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

保留时间 [min]	k'	峰面积 [nRIU*s]	峰高 [nRIU]	对称因子	峰宽 [min]	塔板数	分离度	选择性
9.277	-	138.18439	8.41750	4.37	0.3036	5173	-	-
9.500	-	179.87669	10.63750	1.10	-	-	-	1.02
9.824	-	126.95391	9.90750	1.98	-	-	-	1.03
10.195	-	309.12796	32.04000	0.00	0.1458	27089	-	1.04
10.640	-	1.05482e6	6.82963e4	0.89	0.2412	10780	1.35	1.04
11.621	-	202.90878	25.42000	0.31	-	-	-	1.09
11.783	-	234.03438	24.44625	0.53	-	-	-	1.01

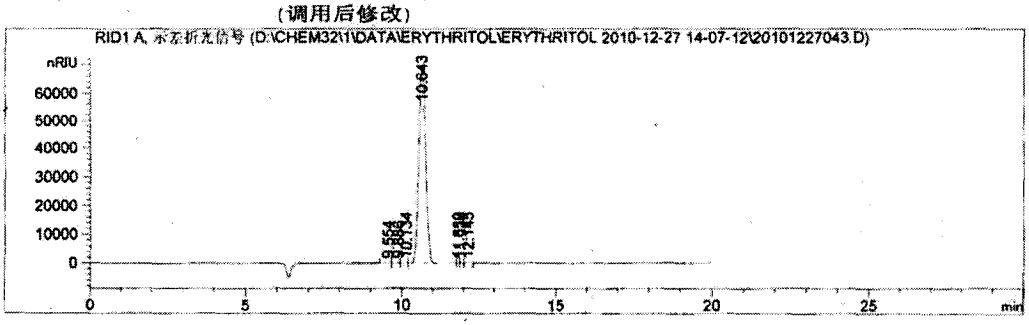
*** 报告结束 ***

质监部

仪器 1 2010-12-23 4:18:50 下午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\20101227043.D
样品名称: 20101204-3

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 4
进样日期	: 2010-12-27 2:52:22 下午	进样次数	: 3
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\ERYTHRITOL.M		
最后修改	: 2010-12-27 11:29:10 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\20101227043.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2011-4-6 3:53:40 下午 (调用后修改)		



面积百分比报告(包含性能计算)

乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

保留时间 [min]	k'	峰面积 [nRIU*s]	峰高 [nRIU]	对称因子	峰宽 [min]	塔板数	分离度	选择性
9.554	-	219.67119	11.01000	2.22	-	-	-	-
9.886	-	148.03516	9.59000	3.78	-	-	-	1.03
10.134	-	168.45750	12.88625	2.70	-	-	-	1.03
10.643	-	1.09210e6	6.99396e4	0.89	0.2448	10472	-	1.05
11.830	-	133.95280	20.91000	0.95	-	-	-	1.11
11.934	-	149.05566	20.79750	0.73	-	-	-	1.01
12.145	-	343.89117	21.34250	0.94	-	-	-	1.02

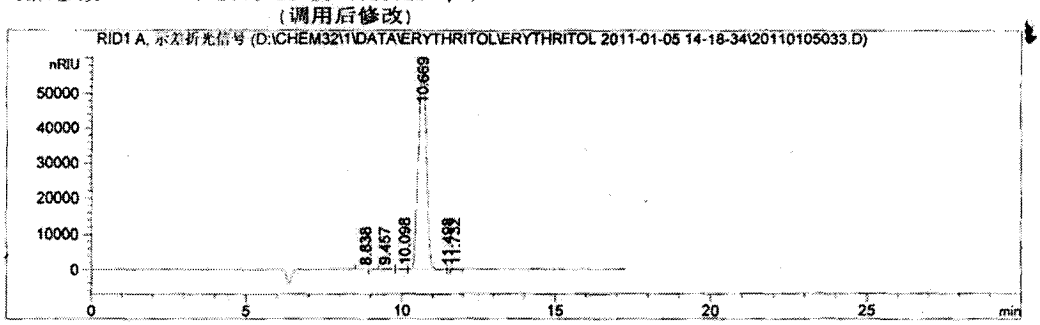
*** 报告结束 ***

仪器 1 2011-4-6 3:53:43 下午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-01-05 14-18-34\20110105033.D
样品名称: 20110103-3

小生物报告

操作者 :　　序列行 : 1
位置 : 样品瓶 3
进样日期 : 05-Jan-11, 15:03:20　　进样次数 : 3
采集方法 : ERYTHRITOL.M
分析方法 : D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-01-05 14-18-34\20110105032.D\DA.M (ERYTHRITOL.M)
最后修改 : 2010-12-23 4:23:22 下午
(调用后修改)



面积百分比报告(包含性能计算)

乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

保留时间 [min]	k'	峰面积 [nRIU*s]	峰高 [nRIU]	对称因子	峰宽 [min]	塔板数	分离度	选择性
8.838	-	120.31622	7.83514	2.89	0.2646	6181	-	-
9.457	-	280.41962	11.72300	0.64	0.4518	2427	1.02	1.07
10.098	-	212.34584	10.57708	3.15	0.3538	4512	0.93	1.07
10.669	-	1.05866e6	5.73672e4	1.10	0.2952	7236	1.03	1.06
11.498	-	137.16292	21.34818	0.50	-	-	-	1.08
11.732	-	418.54865	22.16347	0.48	0.3492	6254	-	1.02

*** 报告结束 ***

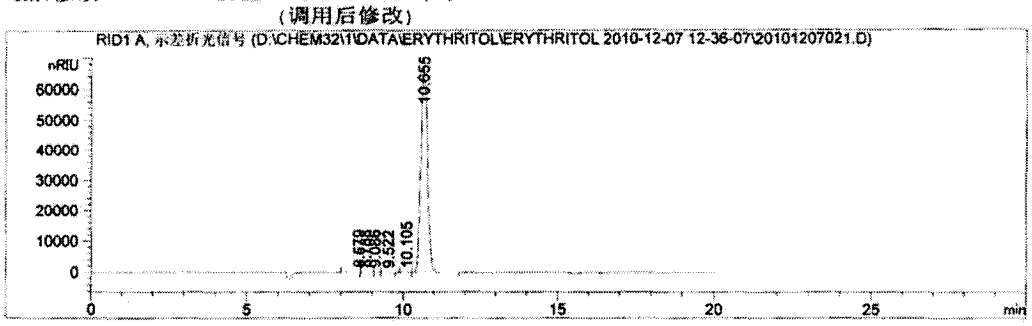
质监部

仪器 1 2010-12-23 4:23:25 下午　　页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\20101207021.D
样品名称: 20101102-1

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 2
进样日期	: 2010-12-7 12:37:27 下午	进样次数	: 1
		进样量	: 10 µl

采集方法 : D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\ERYTHRITOL.M
最后修改 : 2010-12-7 11:00:55 上午
分析方法 : D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\20101207021.D\DA.M (ERYTHRITOL.M)
最后修改 : 2011-4-6 3:58:22 下午 (调用后修改)



面积百分比报告(包含性能计算)

乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

保留时间 [min]	k'	峰面积 [nRIU*s]	峰高 [nRIU]	对称因子	峰宽 [min]	塔板数	分离度	选择性
8.579	-	212.19554	11.54583	6.58	0.2981	4589	-	-
8.788	-	311.37988	13.91551	0.68	-	-	-	1.02
9.086	-	124.55923	10.73450	0.28	-	-	-	1.03
9.522	-	298.73166	13.15422	1.35	-	-	-	1.05
10.105	-	215.43182	11.26290	1.78	-	-	-	1.06
10.655	-	9.88727e5	6.69993e4	0.87	0.2268	12226	-	1.05

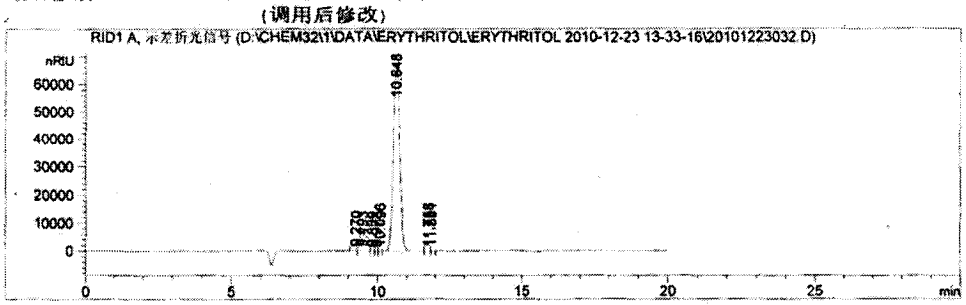
*** 报告结束 ***

质监部

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\20101223032.D
样品名称: 20101124-1

性能报告

操作者 :
仪器 : 仪器 1
进样日期 : 2010-12-23 1:56:43 下午
序列行 : 1
位置 : 样品瓶 3
进样次数 : 2
进样量 : 10 µl
采集方法 : D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\ERYTHRITOL.M
最后修改 : 2010-12-23 10:56:32 上午
分析方法 : D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\20101223032.D\DA.M (ERYTHRITOL.M)
最后修改 : 2011-4-6 3:57:10 下午
(调用后修改)



面积百分比报告(包含性能计算)

乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

保留时间 [min]	k'	峰面积 [nRIU*s]	峰高 [nRIU]	对称因子	峰宽 [min]	塔板数	分离度	选择性
9.270	-	165.57886	12.99750	4.26	-	-	-	-
9.493	-	409.47308	16.39750	0.65	-	-	-	1.02
9.839	-	112.24400	14.04750	1.13	-	-	-	1.04
9.973	-	110.78896	15.34250	1.18	-	-	-	1.01
10.096	-	126.87678	15.53322	0.86	-	-	-	1.01
10.648	-	1.04753e6	6.78295e4	0.89	0.2412	10797	-	1.05
11.758	-	252.76239	19.43000	1.39	-	-	-	1.10
11.851	-	156.50752	17.94000	0.00	-	-	-	1.01

*** 报告结束 ***

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仪器 1 2011-4-6 3:57:13 下午 页 1/1

BEST ORIGINAL COPY

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O'Laughlin(TianJin)Industries Co.,Ltd.

APPENDIX C

Standard Chromatograms

C1 Erythritol , Glycerol and Ribitol Mixed Solution

C 2 Erythritol

C 3 Ribitol

C 4 Glycerol

C 5 In-assay standard recovery check (Erythritol)

O'LAUGHLIN

O'Laughlin(TianJin)Industries Co.,Ltd.

APPENDIX C1

Standard Info	Erythritol	Glycerol	Ribitol
Lot#	13666	15069	A0275980
Purity, %wt ("as is")	99	99	99
Purity, %wt ("dry basis")	N/A	N/A	N/A

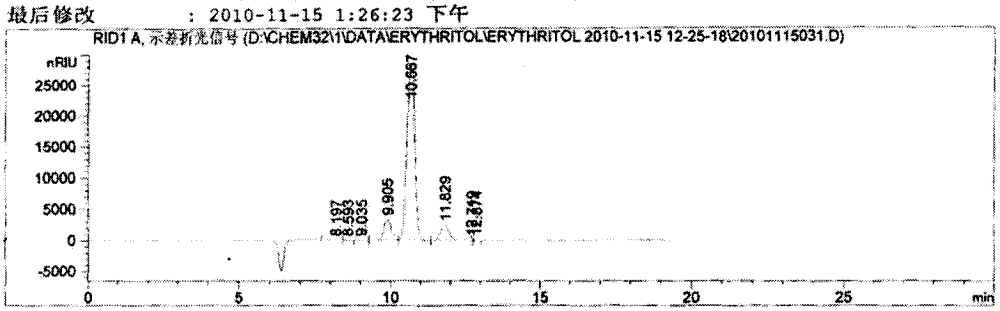
Stock Solution			
Standard	Erythritol	Glycerol	Ribitol
Weight, mg	500	50	50
Volumetric flask volume, mL	100		
Concentration , mg/l	5000	500	500
Water, %wt	-	-	-

Done by: Liu Ying QC **Date:** 11.11.2019
Name, Position

Checked by: Zhang Hua QA **Date:** 11.11.2019
Name, Position

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-11-15 12-25-18\20101115031.D
样品名称: 标样

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 1
进样日期	: 2010-11-15 12:26:41 下午	进样次数	: 1
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-11-15 12-25-18\ERYTHRITOL.M		
最后修改	: 2010-11-15 12:22:59 下午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-11-15 12-25-18\20101115031.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-11-15 1:26:23 下午		



面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	8.197	VV	0.2448	267.05750	13.07394	0.0426
2	8.593	VV	0.2236	203.14186	11.25334	0.0324
3	9.035	VV	0.2467	234.07422	11.57466	0.0373
4	9.905	VV	0.2838	5.87617e4	3362.19824	9.3667
5	10.667	VV	0.2976	5.18826e5	2.83726e4	82.7012
6	11.829	VV	0.3298	4.87912e4	2424.38037	7.7773
7	12.719	VV	0.0543	54.17787	12.64516	8.636e-3
8	12.874	VV	0.1794	212.39398	14.33175	0.0339
总量 :				6.27350e5	3.42220e4	

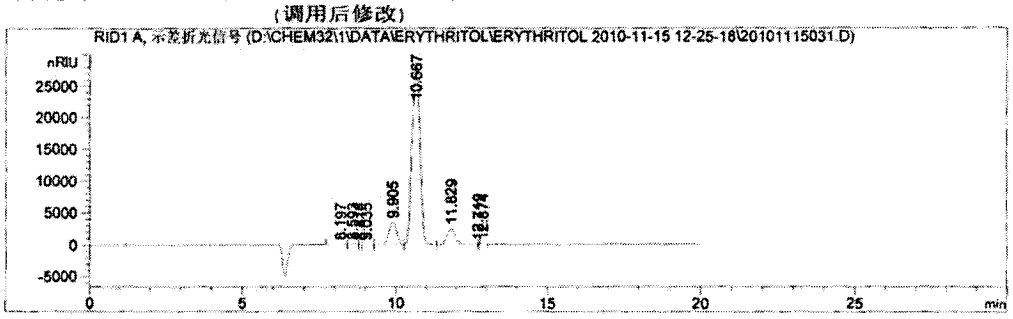
*** 报告结束 ***

质监部

仪器 1 2011-4-7 9:56:45 上午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-11-15 12-25-18\20101115031.D
样品名称: 标样

操作者	:	序列行 :	1
仪器	: 仪器 1	位置 :	样品瓶 1
进样日期	: 2010-11-15 12:26:41 下午	进样次数 :	1
		进样量 :	10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-11-15 12-25-18\ERYTHRITOL.M		
最后修改	: 2010-11-15 12:22:59 下午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-11-15 12-25-18\20101115031.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-11-15 12:53:53 下午 (调用后修改)		



面积百分比报告(包含性能计算)

乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

保留时间 [min]	k'	峰面积 [nRIU*s]	峰高 [nRIU]	对称因子	峰宽 [min]	塔板数	分离度	选择性
8.197	-	267.05750	13.07394	0.87	0.3348	3321	-	-
8.593	-	203.14186	11.25334	1.00	-	-	-	1.05
8.816	-	55.72990	8.47031	0.69	-	-	-	1.03
9.035	-	234.07422	11.57466	0.59	-	-	-	1.02
9.905	-	5.87617e4	3362.19824	1.02	0.2784	7012	-	1.10
10.667	-	5.18826e5	2.83726e4	1.06	0.2928	7353	1.57	1.08
11.829	-	4.87912e4	2424.38037	1.12	0.3168	7724	2.24	1.11
12.719	-	54.17787	12.64516	0.69	-	-	-	1.08
12.874	-	212.39398	14.33175	0.72	-	-	-	1.01

*** 报告结束 ***

质监部

仪器 1 2010-11-15 12:54:03 下午 页 1/1

方法 D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-10-19 14-06-26\2010101901.D\DA.M

校正表

校正数据修改时间	:	2010-11-11 1:23:16 下午
计算	:	面积百分比
相对参比窗口	:	5.000 %
绝对参比窗口	:	0.000 min
相对非参比窗口	:	5.000 %
绝对非参比窗口	:	0.000 min
内标使用乘积因子和稀释因子		
未校正峰	:	未被报告
部分校正	:	是的，标识的峰已重新校正
修正所有保留时间	:	不，只有标识的峰
曲线类型	:	线性
原点	:	含原点
权重	:	均等
重新校正设置	:	
平均响应值	:	平均所有校正值
平均保留时间	:	浮动平均新 75%

校正报告选项 :
序列中重新校正打印输出:
重新校正后的校正表
重新校正后的归一化报告
如果区间循环校正序列已经完成:
第一个周期的结果(结束上一个区间循环校正)

信号 1: RID1 A, 示差折光信号

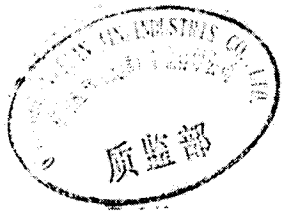
保留时间 [min]	信号	级别	含量 [ng/ul]	峰面积	含量/峰面积	参比	组	名称
10.600	1	1	10.08220	1.02440e6	9.84204e-6			
		2	10.54890	1.06326e6	9.92128e-6			
		3	11.00420	1.13697e6	9.67850e-6			
		4	11.50080	1.17660e6	9.77462e-6			
		5	12.01520	1.22602e6	9.80018e-6			
		6	12.50830	1.26517e6	9.88667e-6			
		7	13.00030	1.30056e6	9.99595e-6			

1警告或错误 :

警告: 当报告生成时打开校正表并修改。

峰加和表

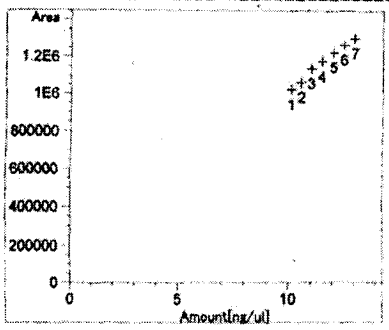
表格中没有条目



仪器 1 2010-11-11 1:27:35 下午

方法: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-10-19 14-06-26\2010101901.D\DA.M

校正曲线



预期 保留时间: 10.600
RID1 A, 示差折光信号
相关性: 0.99962
残留标准误差: 12623.93112
公式: y = mx + b
m: 101293.02507
b: 2836.55179
x: 含量
y: 峰高

质监部

仪器 1 2010-11-11 1:27:35 下午

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O'LAUGHLIN

O'Laughlin(TianJin)Industries Co.,Ltd.

APPENDIX C2

Standard Info	Erythritol
Lot#	13666
Purity, %wt ("as is")	99
Purity, %wt ("dry basis")	N/A

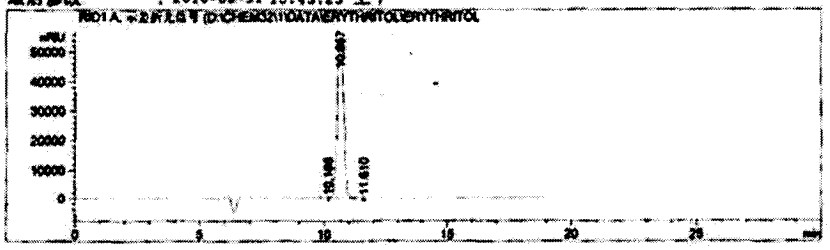
Stock Solution	
Standard	Erythritol
Weight,mg	500.8
Volumetric flask volume, mL	50
Concentration , mg/l	10016
Water, %wt	-

Done by: Lin Ying QC **Date:** 12.11.2019
Name, Position

Checked by: Zhang Hua QA **Date:** 12.11.2019
Name, Position

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-08-31 14-08-24\
样品名称: 赤藓糖醇标准样品

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 11
进样日期	: 2010-08-31 2:10:09 下午	进样次数	: 1
		进样量	: 10 ul
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-08-31 14-08-24\ERYTHRITOL.M		
最后修改	: 2010-08-31 2:19:21 下午 (调用后修改)		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-08-31 14-08-24\D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-08-31 10:43:23 上午		



面积百分比报告

排序	:	信号
校正数据修改时间	:	2010-08-31 9:58:30 上午
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰面积 %	名称
1	10.166	BV	0.1037	240.21144	0.0237	?
2	10.657	VV	0.3039	1.01514e6	99.9661	
3	11.610	VBA	0.0891	103.80231	0.0102	?

总量 : 1.01549e6

1警告或错误 :

警告: 校正警告(参见校正列表)

*** 报告结束 ***

质监部

仪器 1 2010-08-31 2:40:03 下午 第 1/1

O'LAUGHLIN

O'Laughlin(TianJin)Industries Co.,Ltd.

APPENDIX C3

Standard Info	Ribitol
Lot#	A0275980
Purity, %wt ("as is")	99
Purity, %wt ("dry basis")	N/A

Stock Solution	
Standard	Ribitol
Weight,mg	101.6
Volumetric flask volume, mL	50
Concentration , mg/l	1003.2
Water, %wt	-

Done by: Liu Ying **Date:** 12.11.21

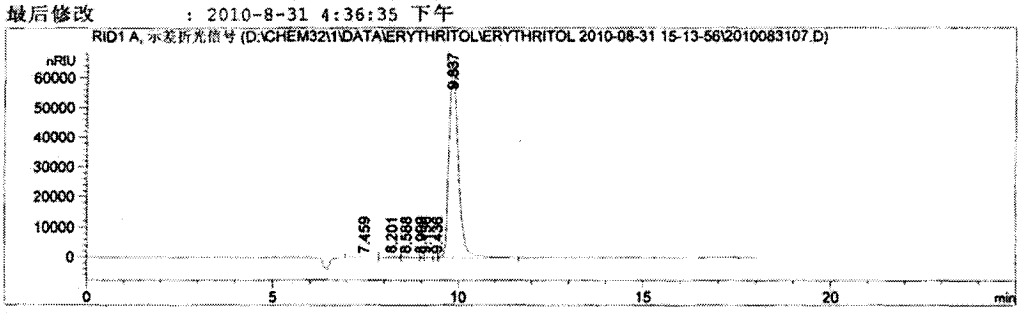
Name, Position

Checked by: ZhangHua **Date:** 12.11.21

Name, Position

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-08-31 15-13-56\2010083107.D
样品名称: 核糖醇

操作者 :
仪器 : 仪器 1
进样日期 : 2010-8-31 3:56:43 下午
采集方法 : D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-08-31 15-13-56\ERYTHRITOL.M
最后修改 : 2010-8-31 3:55:12 下午 (调用后修改)
分析方法 : D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-08-31 15-13-56\2010083107.D\DA.M (ERYTHRITOL.M)
最后修改 : 2010-8-31 4:36:35 下午
序列行 : 3
位置 : 样品瓶 3
进样次数 : 1
进样量 : 10 µl



面积百分比报告

排序 : 信号
乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	7.459	BV	0.5133	2279.85620	52.71000	0.1971
2	8.201	VV	0.2882	5546.84473	278.85999	0.4795
3	8.588	VV	0.3098	3322.10083	148.98250	0.2872
4	8.999	VV	0.0935	452.07761	62.12322	0.0391
5	9.130	VV	0.1736	864.30414	61.13000	0.0747
6	9.436	VV	0.1035	478.59607	57.54750	0.0414
7	9.837	VBA	0.2677	1.14383e6	6.50700e4	98.8810
总量 :				1.15678e6	6.57314e4	

*** 报告结束 ***

仪器 1 2011-4-7 9:41:36 上午 页 1/1

O'LAUGHLIN

O'Laughlin(TianJin)Industries Co.,Ltd.

APPENDIX C4

Standard Info	Glycerol
Lot#	15069
Purity, %wt ("as is")	99
Purity, %wt ("dry basis")	N/A

Stock Solution	
Standard	Glycerol
Weight,mg	500.9
Volumetric flask volume, mL	50
Concentration , mg/l	10018
Water, %wt	-

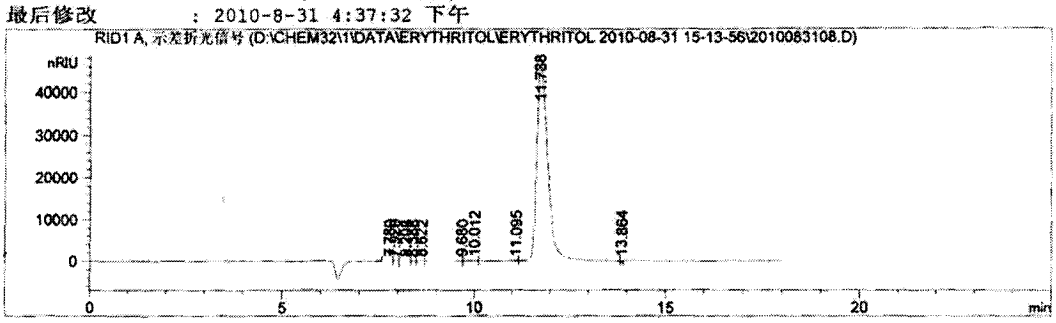
Done by: Liu Ying **Date:** 13.11.24
Name, Position

Checked by: Zhang Hua **Date:** 13.11.24
Name, Position

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-08-31 15-13-56\2010083108.D
样品名称: 丙三醇

操作者 :
仪器 : 仪器 1
进样日期 : 2010-8-31 4:16:20 下午
采集方法 : D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-08-31 15-13-56\ERYTHRITOL.M
最后修改 : 2010-8-31 4:14:47 下午 (调用后修改)
分析方法 : D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-08-31 15-13-56\2010083108.D\DA.M (ERYTHRITOL.M)
最后修改 : 2010-8-31 4:37:32 下午

序列行 : 4
位置 : 样品瓶 4
进样次数 : 1
进样量 : 10 µl



面积百分比报告

排序 : 信号
乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	7.780	BV	0.1281	38.82303	3.72500	4.091e-3
2	7.920	VV	0.1063	15.44157	2.42000	1.627e-3
3	8.208	VV	0.1586	39.85686	3.10000	4.200e-3
4	8.388	VV	0.0899	15.09111	2.11000	1.590e-3
5	8.622	VV	0.1273	38.13966	3.96750	4.019e-3
6	9.680	VV	0.3882	1093.52515	33.41875	0.1152
7	10.012	VV	0.2809	936.82440	41.46500	0.0987
8	11.095	VV	0.6137	3427.25415	66.32000	0.3611
9	11.738	VV	0.3241	9.42963e5	4.62822e4	99.3621
10	13.864	VBA	0.0664	448.41721	90.53625	0.0473
总量 :				9.49017e5	4.65292e4	

*** 报告结束 ***

仪器 1 2011-4-7 9:55:31 上午 页 1/1

O'LAUGHLIN

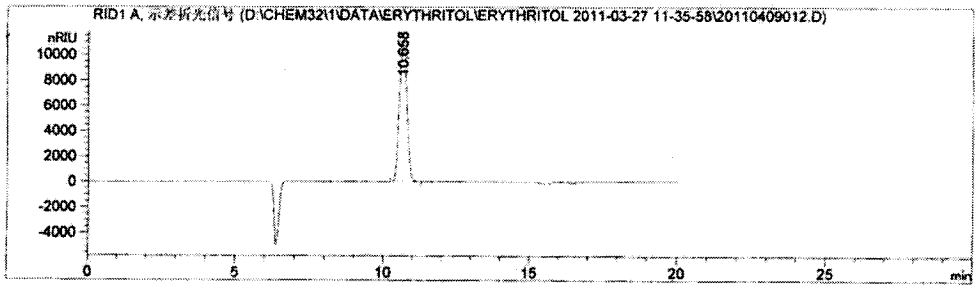
O'Laughlin(TianJin)Industries Co.,Ltd.

APPENDIX C5

In-assay standard recovery check (Erythritol)

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-03-27 11-35-58\20110409012.D
样品名称: Erythritol

操作者	:	序列行 :	1
仪器	: 仪器 1	位置 :	样品瓶 1
进样日期	: 2011-3-27 11:59:21 上午	进样次数 :	2
		进样量 :	10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-03-27 11-35-58\ERYTHRITOL.M		
最后修改	: 2011-3-27 11:35:55 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-03-27 11-35-58\20110409012.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2011-3-27 1:55:58 下午		
样品信息	: Erythritol 2012ng/ul		



外标法报告

排序	:	信号
校正数据修改时间	:	2011年3月27日 1:55:51 下午
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

保留时间 [min]	类型	峰面积 [nRIU*s]	含量/峰面积	含量 [ng/ul]	组	名称
10.658	BV	2.02052e5	9.98519e-3	2017.53174		

总量: 2017.53174

1警告或错误 :

警告: 校正警告(参见校正列表)

*** 报告结束 ***

仪器 1 2011-3-27 1:58:03 下午 页 1/1

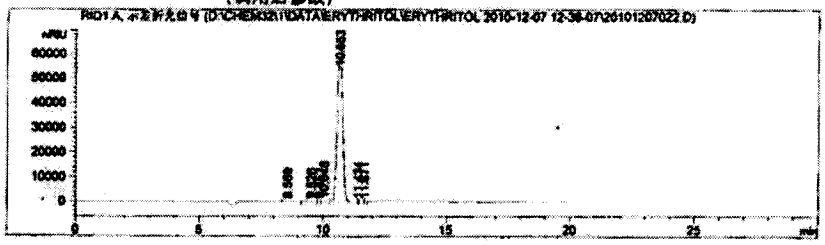
O'LAUGHLIN

O'Laughlin(TianJin)Industries Co.,Ltd.

Sample Chromatograms

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\20101207022.D
样品名称: 20101102-1(A)

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 2
进样日期	: 2010-12-7 12:59:02 下午	进样次数	: 2
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\ERYTHRITOL.M		
最后修改	: 2010-12-7 11:00:55 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\20101207022.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-11-22 10:20:00 上午 (调用后修改)		



面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

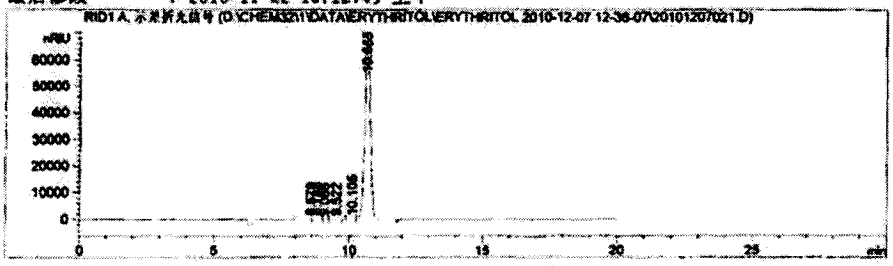
信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	8.569	VV	0.3553	501.53134	17.31250	0.0506
2	9.526	VV	0.2080	130.00743	7.61000	0.0131
3	9.853	VV	0.0984	32.10489	4.27750	3.239e-3
4	10.048	VV	0.1982	137.58890	8.97750	0.0139
5	10.653	VF	0.2327	9.89996e5	6.70777e4	99.8749
6	11.434	VF	0.2047	318.18527	25.91000	0.0321
7	11.671	VBA	0.1181	121.00320	17.07000	0.0122
总量 :				9.91236e5	6.71589e4	

*** 报告结束 ***

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\20101207021.D
样品名称: 20101102-1(B)

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 2
进样日期	: 2010-12-7 12:37:27 下午	进样次数	: 1
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\ERYTHRITOL.M		
最后修改	: 2010-12-7 11:00:55 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-07 12-36-07\20101207021.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-11-22 10:12:49 上午		



面积百分比报告

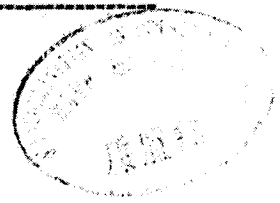
排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

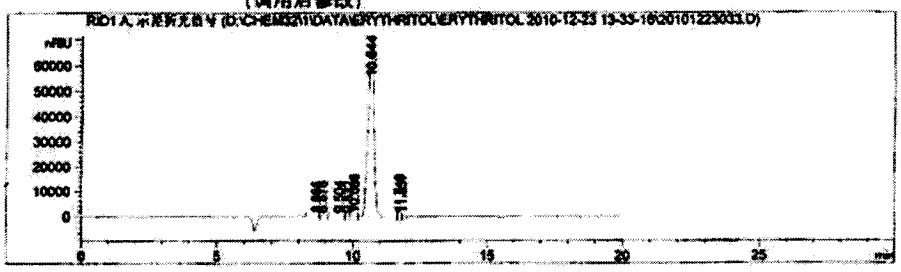
峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	8.579	BV	0.2231	212.19554	11.54583	0.0214
2	8.788	VV	0.2654	311.37988	13.91551	0.0315
3	9.086	VV	0.1483	124.55923	10.73450	0.0126
4	9.522	VV	0.2779	298.73166	13.15422	0.0302
5	10.105	VV	0.2383	215.43182	11.26290	0.0218
6	10.655	VV	0.2348	9.88727e5	6.69993e4	99.8826
总量 :				9.89889e5	6.70600e4	

*** 报告结束 ***



数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\20101223033.D
样品名称: 20101124-1 (A)

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 3
进样日期	: 2010-12-23 2:18:18 下午	进样次数	: 3
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\ERYTHRITOL.M		
最后修改	: 2010-12-23 10:56:32 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\20101223033.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-11-22 10:24:39 上午 (调用后修改)		



面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	8.665	VV	0.2952	246.84079	9.97542	0.0235
2	8.878	VV	0.2004	156.20390	9.83667	0.0149
3	9.504	VV	0.3213	353.12103	13.17667	0.0336
4	9.832	VV	0.1255	96.77934	9.66417	9.221e-3
5	10.066	VV	0.1997	204.68205	12.49667	0.0195
6	10.644	VV	0.2450	1.04826e6	6.78819e4	99.8771
7	11.740	VF	0.1190	130.80519	13.56542	0.0125
8	11.837	VV	0.1427	101.71192	11.87667	9.691e-3
总量 :				1.04955e6	6.79625e4	

*** 报告结束 ***

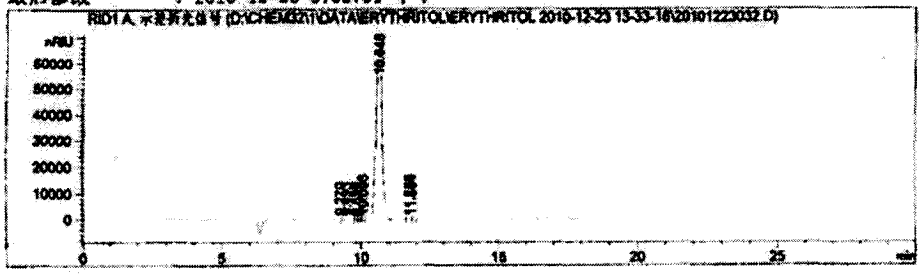
质监部

仪器 1 2010-11-22 10:24:42 上午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\20101223032.D
样品名称: 20101124-1(B)

操作者 :
仪器 : 仪器 1
进样日期 : 2010-12-23 1:56:43 下午
采集方法 : D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\ERYTHRITOL.M
最后修改 : 2010-12-23 10:56:32 上午
分析方法 : D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 13-33-16\20101223032.D\DA.M (ERYTHRITOL.M)
最后修改 : 2010-12-23 3:02:51 下午

序列行 : 1
位置 : 样品瓶 3
进样次数 : 2
进样量 : 10 µl



面积百分比报告

排序 : 信号
乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	9.270	VV	0.1616	165.57886	12.99750	0.0158
2	9.493	VV	0.2957	409.47308	16.39750	0.0390
3	9.839	VV	0.0975	112.24400	14.04750	0.0107
4	9.973	VV	0.0886	110.78896	15.34250	0.0106
5	10.096	VV	0.1018	126.87678	15.53322	0.0121
6	10.648	VV	0.2471	1.04753e6	6.78295e4	99.8728
7	11.758	VF	0.1583	252.76239	19.43000	0.0241
8	11.851	VV	0.1454	156.50752	17.94000	0.0149
总量 :				1.04886e6	6.79412e4	

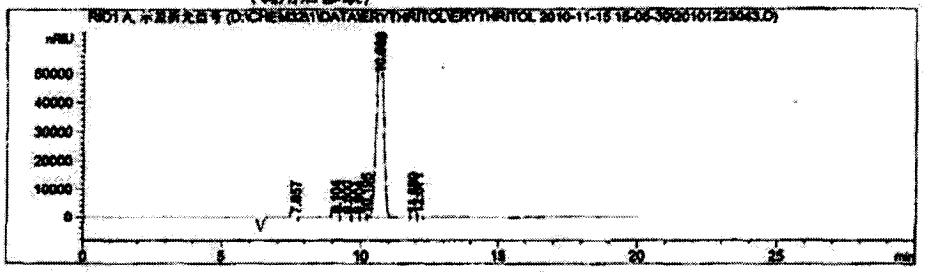
*** 报告结束 ***

质监部

仪器 1 2010-11-22 10:23:04 上午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 15-05-39\20101223043.D
样品名称: 20101126-1 (A)

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 2
进样日期	: 2010-12-23 3:50:28 下午	进样次数	: 3
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 15-05-39\ERYTHRITOL.M		
最后修改	: 2010-12-23 12:22:59 下午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 15-05-39\20101223043.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-12-23 4:14:36 下午 (调用后修改)		



面积百分比报告

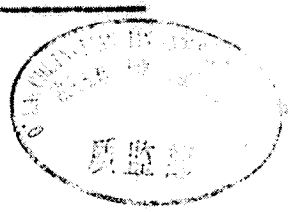
排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	7.657	VV	0.1833	116.50217	7.68875	0.0103
2	9.104	VV	0.1955	128.45776	7.92750	0.0114
3	9.500	VV	0.2526	180.31586	8.54750	0.0160
4	9.904	VV	0.1981	168.93980	10.28500	0.0150
5	10.195	VV	0.1446	274.84894	31.68000	0.0244
6	10.668	VV	0.2997	1.12486e6	6.15117e4	99.8832
7	11.880	VV	0.1851	267.76791	17.70000	0.0238
8	12.071	VBA	0.1401	178.75296	15.60875	0.0159
总量 :				1.12618e6	6.16112e4	

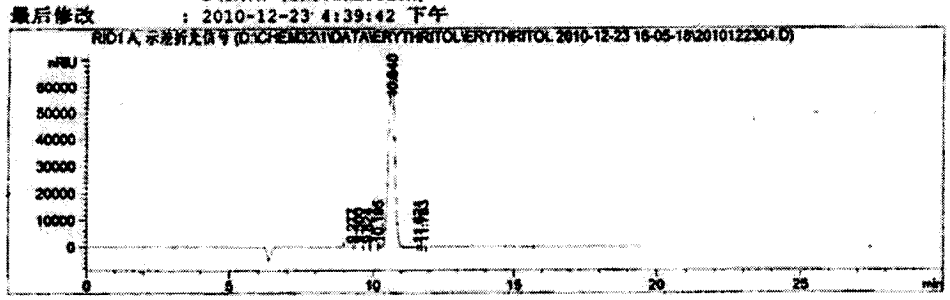
*** 报告结束 ***



仪器 1 2010-11-15 4:15:17 下午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 16-05-18\2010122304.D
样品名称: 20101126-1(B)

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 4
进样日期	: 2010-12-23 4:07:13 下午	进样次数	: 1
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 16-05-18\ERYTHRITOL.M		
最后修改	: 2010-12-23 10:56:32 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-23 16-05-18\2010122304.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-12-23 4:39:42 下午		



面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	9.277	VV	0.2066	138.18439	8.41750	0.0131
2	9.500	VV	0.2016	179.87669	10.63750	0.0170
3	9.824	VV	0.1581	126.95391	9.90750	0.0120
4	10.195	VV	0.1608	309.12796	32.04000	0.0293
5	10.640	VV	0.2471	1.05482e6	6.82963e4	99.8872
6	11.621	VV	0.0996	202.90878	25.42000	0.0192
7	11.783	VV	0.1203	234.03438	24.44625	0.0222
总量 :				1.05601e6	6.84072e4	

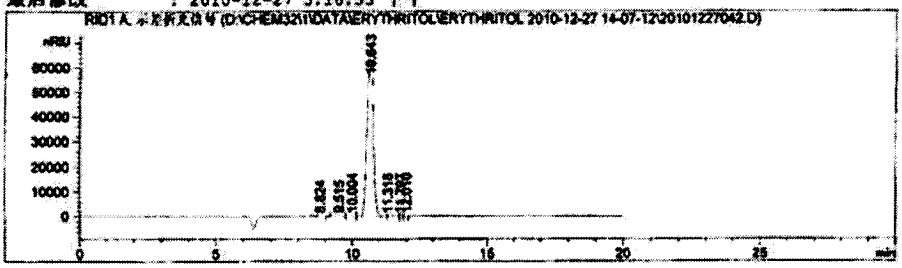
*** 报告结束 ***

质检部

仪器 1 2010-11-22 10:26:46 上午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\20101227042.D
样品名称: 20101204-3(A)

操作者 :
仪器 : 仪器 1
进样日期 : 2010-12-27 2:30:45 下午
采集方法 : D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\ERYTHRITOL.M
最后修改 : 2010-12-27 11:29:10 上午
分析方法 : D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\20101227042.D\DA.M (ERYTHRITOL.M)
最后修改 : 2010-12-27 3:16:53 下午
序列行 : 1
位置 : 样品瓶 4
进样次数 : 2
进样量 : 10 µl



面积百分比报告

排序 : 信号
乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 (min)	类型	峰宽 (min)	峰面积 (nRIU*s)	峰高 (nRIU)	峰面积 %
1	8.824	VV	0.1887	112.93911	7.31875	0.0103
2	9.515	VV	0.2903	236.06911	9.85500	0.0216
3	10.004	VV	0.2438	156.60703	7.62875	0.0143
4	10.643	VF	0.2467	1.09018e6	6.99051e4	99.8858
5	11.318	VV	0.3312	477.14590	24.01000	0.0437
6	11.797	VV	0.1113	117.38412	13.62750	0.0108
7	12.010	VBA	0.1403	146.28223	13.18000	0.0134
总量 :				1.09143e6	6.99807e4	

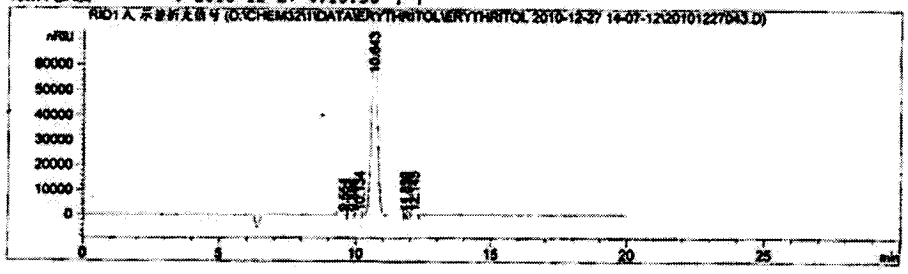
*** 报告结束 ***

质监部

仪器 1 2010-11-22 10:29:52 上午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\20101227043.D
样品名称: 20101204-3(8)

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 4
进样日期	: 2010-12-27 2:52:22 下午	进样次数	: 3
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\ERYTHRITOL.M		
最后修改	: 2010-12-27 11:29:10 上午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2010-12-27 14-07-12\20101227043.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-12-27 4:15:36 下午		



面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

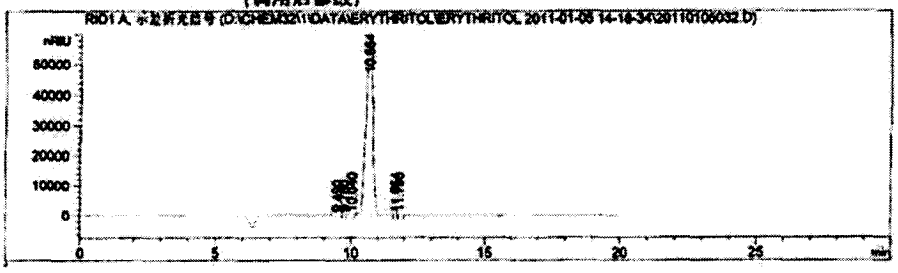
峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	9.554	VV	0.2393	219.67119	11.01000	0.0201
2	9.886	VV	0.1844	148.03516	9.59000	0.0135
3	10.134	VV	0.1633	168.45750	12.88625	0.0154
4	10.643	VV	0.2491	1.09210e6	6.99396e4	99.8936
5	11.830	VV	0.0834	133.95280	20.91000	0.0123
6	11.934	VV	0.0987	149.05566	20.79750	0.0136
7	12.145	VV	0.1988	343.89117	21.34250	0.0315
总量 :				1.09327e6	7.00362e4	

*** 报告结束 ***

仪器 1 2010-11-22 10:29:03 上午 页 1/1

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-01-05 14-18-34\20110105032.D
样品名称: 20110103-3 (A)

操作者	:	序列行	: 1
仪器	: 仪器 1	位置	: 样品瓶 3
进样日期	: 2011-1-5 2:41:41 下午	进样次数	: 2
		进样量	: 10 µl
采集方法	: D:\Chem32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-01-05 14-18-34\ERYTHRITOL.M		
最后修改	: 2011-1-5 1:31:09 下午		
分析方法	: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-01-05 14-18-34\20110105032.D\DA.M (ERYTHRITOL.M)		
最后修改	: 2010-11-22 10:39:49 上午 (调用后修改)		



面积百分比报告

排序	:	信号
乘积因子	:	1.0000
稀释因子	:	1.0000

内标使用乘积因子和稀释因子

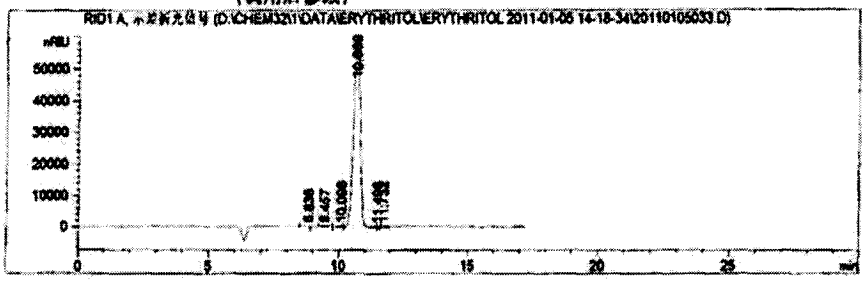
信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	9.490	VV	0.2543	361.27054	17.30804	0.0341
2	9.760	VV	0.1164	131.44598	14.23581	0.0124
3	10.040	VV	0.1737	234.08492	16.76373	0.0221
4	10.664	VV	0.3018	1.05761e6	5.72823e4	99.8844
5	11.664	VV	0.1135	191.97253	22.77706	0.0181
6	11.790	VBA	0.1663	304.95667	22.56727	0.0288
总量 :				1.05884e6	5.73760e4	

*** 报告结束 ***

数据文件: D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-01-05 14-18-34\20110105033.D
样品名称: 20110103-3(B)

操作者 : 序列行 : 1
位置 : 样品瓶 3
进样日期 : 05-Jan-11, 15:03:20 进样次数 : 3
采集方法 : ERYTHRITOL.M
分析方法 : D:\CHEM32\1\DATA\ERYTHRITOL\ERYTHRITOL 2011-01-05 14-18-34\20110105032.D\DA.M (ERYTHRITOL.M)
最后修改 : 2010-11-22 10:36:43 上午
(调用后修改)



面积百分比报告

排序 : 信号
乘积因子 : 1.0000
稀释因子 : 1.0000
内标使用乘积因子和稀释因子

信号 1: RID1 A, 示差折光信号

峰 #	保留时间 [min]	类型	峰宽 [min]	峰面积 [nRIU*s]	峰高 [nRIU]	峰面积 %
1	8.838	BV	0.1900	120.31622	7.83514	0.0114
2	9.457	VV	0.2856	280.41962	11.72300	0.0265
3	10.098	VV	0.2429	212.34584	10.57708	0.0200
4	10.669	VV	0.3017	1.05866e6	5.73672e4	99.8897
5	11.498	VB	0.1071	137.16292	21.34818	0.0129
6	11.732	BBA	0.2290	418.54865	22.16347	0.0395
总量 :				1.05983e6	5.74409e4	

*** 报告结束 ***

仪器 1 2010-11-22 10:36:46 上午 页 1/1

O'LAUGHLIN

O'Laughlin(TianJin)Industries Co.,Ltd.

Standard Info	Lot# (b) (4)	
	Duplicate A	Duplicate B
Sample ID	A	B
Weight,mg	5034	5025
Volumetric flask volume, mL	50	50
Concentration , mg/l	10068	10050
Water, %wt	-	-

Standard Info	Lot# (b) (4)	
	Duplicate A	Duplicate B
Sample ID	A	B
Weight,mg	5018	5020
Volumetric flask volume, mL	50	50
Concentration , mg/l	10036	1004
Water, %wt	-	-

Standard Info	Lot# (b) (4)	
	Duplicate A	Duplicate B
Sample ID	A	B
Weight,mg	512	5078
Volumetric flask volume, mL	50	50.
Concentration , mg/l	10240	1019
Water, %wt	-	-

Done by: Lin Ying **Date:** 19.11.24
Name, Position

Checked by: zhang Hua **Date:** 19.11.24
Name, Position

O'LAUGHLIN

O'Laughlin(TianJin)Industries Co.,Ltd.

Standard Info	Lot# (b) (4)	
	Duplicate A	Duplicate B
Sample ID	A	B
Weight,mg	503.2	502.8
Volumetric flask volume, mL	50	50
Concentration mg/l	10064	10056
Water, %wt	-	-

Standard Info	Lot# (b) (4)	
	Duplicate A	Duplicate B
Sample ID	A	B
Weight,mg	501.5	502.1
Volumetric flask volume, mL	50	50
Concentration , mg/l	10036	10042
Water, %wt	-	-

Done by: Liu Ying **Date:** 14.11.24.
Name, Position

Checked by: Zhang Nua **Date:** 14.11.24
Name, Position

APPENDIX E-2

Certificates of Analysis of Five Production Batches of

O'Laughlin's Erythritol Product Code: 775-2019

O'LAUGHLIN (TIANJIN) INDUSTRIES Co.,Ltd.

CERTIFICATE OF ANALYSIS

Document number:

Product Name Erythritol Lot Number (b) (4)

Product Code 775-2019 Product DATE 2010.11.24

ITEM	STANDARD	RESULTS (each batch)
INSPECTION DATE		2010.11.25
WEIGHT OF EACH BATCH		6T
Odor	**Characteristic of erythritol with no off odors**	Meets requirements
Taste	**Clean, sweet taste; slightly cooling**	Meets requirements
Appearance	**White crystal**	Meets requirements
Free Flowing	**Yes**	Meets requirements
ASSAY %	**Not less than 99.5% and not more than 100.5% of $C_4H_{10}O_4$, calculated on the dried basis**	99.87
Ribitol and Glycerol,%(w/w)	**≤0.1**	Not Detected
Moisture Content (%) by Loss on Drying	**<0.2**	0.022
Pd (ppm)	**≤0.5**	<0.1
PH (30%, Solution)	**5-7**	5.6
Melting Point,℃	**119-123**	119.0-120.6
Reducing Sugars,%(w/w)	**≤0.3**	<0.2
Residue on Ignition	**≤0.1**	0.08
Total Aerobic Plate Count (cfu/g)	**≤300**	<10
Total Aerobic Yeast Count (cfu/g)	**≤50**	<10
Total Aerobic Mold Count (cfu/g)	**≤50**	<10
Coliform(MPN/100g)	**Negative**	Meets requirements
E.Coli(MPN/100g)	**Negative**	Meets requirements

ELEASED BY/ DATE: 张经

O'LAUGHLIN (TIANJIN) INDUSTRIES Co.,Ltd.

CERTIFICATE OF ANALYSIS

Document number:

Product Name Erythritol Lot Number (b) (4)

Product Code 775-2019 Product DATE 2010.11.02

ITEM	STANDARD	RESULTS (each batch)
INSPECTION DATE		2010.11.03
WEIGHT OF EACH BATCH		6T
Odor	**Characteristic of erythritol with no off odors**	Meets requirements
Taste	**Clean, sweet taste; slightly cooling**	Meets requirements
Appearance	**White crystal**	Meets requirements
Free Flowing	**Yes**	Meets requirements
ASSAY %	**Not less than 99.5% and not more than 100.5% of $C_4H_{10}O_4$, calculated on the dried basis**	99.88
Ribitol and Glycerol,%(w/w)	**≤0.1**	Not Detected
Moisture Content (%) by Loss on Drying	**<0.2**	0.049
Heavy metal (As Pb) (ppm)	**≤0.5**	<0.1
PH（30%，Solution）	**5-7**	5.5
Melting Point,℃	**119-123**	119.0-120.4
Reducing Sugars,%(w/w)	**≤0.3**	<0.2
Residue on Ignition	**≤0.1**	0.064
Total Aerobic Plate Count（cfu/g）	**≤300**	<10
Total Aerobic Yeast Count（cfu/g）	**≤50**	<10
Total Aerobic Mold Count（cfu/g）	**≤50**	<10
Coliform(MPN/100g)	**Negative**	Meets requirements
E.Coli(MPN/100g)	**Negative**	Meets requirements

ELEASED BY/ DATE: 樊琴

O'LAUGHLIN (TIANJIN) INDUSTRIES Co.,Ltd.

CERTIFICATE OF ANALYSIS

Document number:
Product Name Erythritol Lot Number (b) (4)
Product Code 775-2019 Product DATE 2011.01.03

ITEM	STANDARD	RESULTS (each batch)
INSPECTION DATE		2011.01.04
WEIGHT OF EACH BATCH		4T
Odor	**Characteristic of erythritol with no off odors**	Meets requirements
Taste	**Clean, sweet taste; slightly cooling**	Meets requirements
Appearance	**White crystal**	Meets requirements
Free Flowing	**Yes**	Meets requirements
ASSAY %	**Not less than 99.5% and not more than 100.5% of $C_4H_{10}O_4$, calculated on the dried basis**	99.89
Ribitol and Glycerol,%(w/w)	**≤0.1**	Not Detected
Moisture Content (%) by Loss on Drying	**<0.2**	0.029
Pd (ppm)	**≤0.5**	<0.1
PH (30%, Solution)	**5-7**	5.41
Melting Point,℃	**119-123**	119.2-120.7
Reducing Sugars,%(w/w)	**≤0.3**	<0.2
Residue on Ignition	**≤0.1**	0.088
Total Aerobic Plate Count (cfu/g)	**≤300**	<10
Total Aerobic Yeast Count (cfu/g)	**≤50**	<10
Total Aerobic Mold Count (cfu/g)	**≤50**	<10
Coliform(MPN/100g)	**Negative**	Meets requirements
E.Coli(MPN/100g)	**Negative**	Meets requirements

RELEASED BY/ DATE: 张华

O'LAUGHLIN (TIANJIN) INDUSTRIES Co.,Ltd.

CERTIFICATE OF ANALYSIS

Document number:
Product Name Erythritol Lot Number (b) (4)
Product Code 775-2019 Product DATE 2010.11.26

ITEM	STANDARD	RESULTS (each batch)
INSPECTION DATE		2010.11.29
WEIGHT OF EACH BATCH		7T
Odor	**Characteristic of erythritol with no off odors**	Meets requirements
Taste	**Clean, sweet taste; slightly cooling**	Meets requirements
Appearance	**White crystal**	Meets requirements
Free Flowing	**Yes**	Meets requirements
ASSAY %	**Not less than 99.5% and not more than 100.5% of $C_4H_{10}O_4$, calculated on the dried basis**	99.89
Ribitol and Glycerol,%(w/w)	**≤0.1**	Not Detected
Moisture Content (%) by Loss on Drying	**<0.2**	0.033
Pd (ppm)	**≤0.5**	<0.1
PH (30%. Solution)	**5-7**	5.6
Melting Point,℃	**119-123**	119.0-120.3
Reducing Sugars,%(w/w)	**≤0.3**	<0.2
Residue on Ignition	**≤0.1**	0.063
Total Aerobic Plate Count (cfu/g)	**≤300**	<10
Total Aerobic Yeast Count (cfu/g)	**≤50**	<10
Total Aerobic Mold Count (cfu/g)	**≤50**	<10
Coliform(MPN/100g)	**Negative**	Meets requirements
E.Coli(MPN/100g)	**Negative**	Meets requirements

ELEASED BY/ DATE: (b) (6)

O'LAUGHLIN (TIANJIN) INDUSTRIES Co.,Ltd.

CERTIFICATE OF ANALYSIS

Document number:
Product Name Erythritol Lot Number (b) (4)
Product Code 775-2019 Product DATE 2010.12.04

ITEM	STANDARD	RESULTS (each batch)
INSPECTION DATE		2010.12.06
WEIGHT OF EACH BATCH		5T
Odor	**Characteristic of erythritol with no off odors**	Meets requirements
Taste	**Clean, sweet taste; slightly cooling**	Meets requirements
Appearance	**White crystal**	Meets requirements
Free Flowing	**Yes**	Meets requirements
ASSAY %	**Not less than 99.5% and not more than 100.5% of $C_4H_{10}O_4$, calculated on the dried basis**	99.89
Ribitol and Glycerol,%(w/w)	**≤0.1**	Not Detected
Moisture Content (%) by Loss on Drying	**<0.2**	0.026
Pd (ppm)	**≤0.5**	<0.1
PH (30%, Solution)	**5-7**	5.6
Melting Point,℃	**119-123**	119.0-120.5
Reducing Sugars,%(w/w)	**≤0.3**	<0.2
Residue on Ignition	**≤0.1**	0.067
Total Aerobic Plate Count (cfu/g)	**≤300**	<10
Total Aerobic Yeast Count (cfu/g)	**≤50**	<10
Total Aerobic Mold Count (cfu/g)	**≤50**	<10
Coliform(MPN/100g)	**Negative**	Meets requirements
E.Coli(MPN/100g)	**Negative**	Meets requirements

ELEASED BY/ DATE: (b) (6)

APPENDIX F

Pesticide Test Report No. TJFDO110400701FD on Erythritol

SGS

Test Report **No: TJFDO110400701FD** **Date: May 16 2011**

Client name: o'laughlin(tianjin)industries co., ltd.
Client address: Da Juan zi Industrial Zone, Jing Wu Town, Xi Qing District, Tian Jin, China

The following sample(s) was/were submitted by/ on behalf of the client as (except SGS Reference No. & SGS Job No. & Date of receipt & Testing period):

Sample name: Erythritol
Batch No./Date: /
Manufacturer: o'laughlin(tianjin)industries co., ltd.
SGS reference No.: SHAFD1106210901
SGS job No.: TJFDO110400701FD
Date of receipt: May 04 2011
Testing period: May 04 2011 ~ May 12 2011

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
302 items Scan

TEST METHOD(S):
SGS In house method

TEST RESULT(S):
Please refer to the next page(s)

SAMPLE DESCRIPTION: White powder in bag

Signed for and on behalf of SGS

(b) (6)

Authorized Signature

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TJFD 007320

SGS

Test Report **No: TJFDO110400701FD** **Date: May 16 2011**

TEST RESULT(S):

Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
1	2-phenyl-phenol	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
2	acrinathrin	With reference to US FDA PAM, GB/T 19648-2006	0.1	N
3	alachlor	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
4	aldrin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
5	allethrin	With reference to US FDA PAM, GB/T 19648-2006	0.03	N
6	allidochlor	With reference to US FDA PAM, GB/T 19648-2006	0.05	N
7	ametryn	With reference to US FDA PAM, GB/T 19648-2006	0.03	N
8	anilofos	With reference to US FDA PAM, GB/T 19648-2006	0.05	N
9	azinophos ethyl	With reference to US FDA PAM, GB/T 19648-2006	0.02	N
10	benalaxyl	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
11	benfluralin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
12	α -BHC	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
13	β -BHC	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
14	γ -BHC/lindan	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
15	δ -BHC	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
16	bifenthrin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
17	bromophos ethyl	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
18	Bromophos-methyl	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
19	bromopropylate	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
20	butachlor	With reference to US FDA PAM, GB/T 19648-2006	0.01	N

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TJFD 007319

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Test Report **No: TJFDO110400701FD** **Date: May 16 2011**

Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
21	butamifos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
22	cadusafos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
23	captafol	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
24	carbophenothion	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
25	cis-chlordane	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
26	Oxy-chlordane	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
27	trans-chlordane	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
28	chlorfenapyr	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
29	chlorfenvinphos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
30	chlorobenzilate	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
31	Chlorothalonil	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
32	chlorpropham	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
33	chlorpyrifos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
34	chlorpyrifos methyl	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
35	chlorthal-dimethyl	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
36	clodinafop-propargyl	With reference to US FDA PAM, GB/T 19648-2006	0.03	N
37	clomazone	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
38	cloquintocet-mexyl	With reference to US FDA PAM, GB/T 19648-2006	0.1	N
39	cyanophos	With reference to US FDA PAM, GB/T 19648-2006	0.05	N
40	cyfluthrin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
41	Lambda-Cyhalothrin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N

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TJFD 007318

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Test Report **No: TJFDO110400701FD** **Date: May 16 2011**

Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
42	cypermethrin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
43	cyproconazole	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
44	cyprodinil	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
45	o, p'-DDD	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
46	p, p'-DDD	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
47	o, p'-DDE	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
48	p, p'-DDE	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
49	o, p'-DDT	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
50	p, p'-DDT	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
51	Deltamethrin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
52	diazinon	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
53	dichlofenthion	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
54	dichlofluanid	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
55	diclobutrazol	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
56	diclofop-methyl	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
57	dicloran	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
58	dicofol	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
59	dicrotophos	With reference to US FDA PAM, GB/T 19648-2006	0.02	N
60	dieldrin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
61	dimethenamid	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
62	dimethipin	With reference to US FDA PAM, GB/T 19648-2006	0.05	N

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Test Report **No: TJFDO110400701FD** **Date: May 16 2011**

Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
63	dimethylvinphos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
64	diphenamid	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
65	diphenylamine	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
66	dithiopyr	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
67	edifenphos	With reference to US FDA PAM, GB/T 19648-2006	0.03	N
68	α -endosulfan	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
69	β -endosulfan	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
70	endosulfan sulfate	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
71	endrin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
72	EPN	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
73	esfenvalerate	With reference to US FDA PAM, GB/T 19648-2006	0.05	N
74	ethalfluralin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
75	ethion	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
76	ethofumesate	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
77	ethoprophos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
78	etofenprox	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
79	etridiazole	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
80	etrimfos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
81	fenamiphos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
82	fenarimol	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
83	fenchlorphos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N

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Test Report **No: TJFDO110400701FD** **Date: May 16 2011**

Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
84	fenitrothion	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
85	fenpropathrin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
86	fensulfothion	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
87	fenthion	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
88	fenvalerate	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
89	fipronil	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
90	flucythrinate	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
91	fluquinconazole	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
92	flurochloridone	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
93	flusilazole	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
94	flutolanil	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
95	tau-fluvalinate	With reference to US FDA PAM, GB/T 19648-2006	0.05	N
96	fonofos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
97	formothion	With reference to US FDA PAM, GB/T 19648-2006	0.02	N
98	fosthiazate	With reference to US FDA PAM, GB/T 19648-2006	0.03	N
99	furalaxyl	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
100	halfenprox	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
101	heptachlor	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
102	heptachloroepoxide	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
103	heptenophos	With reference to US FDA PAM, GB/T 19648-2006	0 01	N
104	hexachlorobenzene	With reference to US FDA PAM, GB/T 19648-2006	0.01	N

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Test Report **No: TJFDO110400701FD** **Date: May 16 2011**

Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
105	iprodione	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
106	isazophos	With reference to US FDA PAM, GB/T 19648-2006	0.03	N
107	isocarbophos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
108	isodrin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
109	isofenphos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
110	mepronil	With reference to US FDA PAM, GB/T 19648-2006	0.03	N
111	methacrifos	With reference to US FDA PAM, GB/T 19648-2006	0.03	N
112	methoxychlor	With reference to US FDA PAM, GB/T 19648-2006	0.02	N
113	methyl-pentachloroph enyl sulfide	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
114	mirex	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
115	myclobutanil	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
116	napropamide	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
117	nitrothal-isopropyl	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
118	Paclobutrazol	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
119	parathion	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
120	parathion methyl	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
121	penconazole	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
122	pendimethalin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
123	pentachloroaniline	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
124	pentachloroanisole	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
125	permethrin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N

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Test Report **No: TJFDO110400701FD** **Date: May 16 2011**

Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
126	phenthoate	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
127	phorate	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
128	phosphamidon	With reference to US FDA PAM, GB/T 19648-2006	0.03	N
129	piperophos	With reference to US FDA PAM GB/T 19648-2006	0.01	N
130	pirimiphos-ethyl	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
131	pirimiphos-methyl	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
132	procymidone	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
133	profenophos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
134	prometryn	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
135	propanil	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
136	propaphos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
137	propham	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
138	propiconazole	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
139	propyzamide	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
140	prothiofos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
141	pyraclofos	With reference to US FDA PAM, GB/T 19648-2006	0.03	N
142	pyrazophos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
143	Pyrethrin I	With reference to US FDA PAM, GB/T 19648-2006	0.03	NR
144	quinalphos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
145	quintozene	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
146	S-421	With reference to US FDA PAM, GB/T 19648-2006	0.01	N

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Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
147	safrotin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
148	salithion	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
149	sulfotep	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
150	tecnazene	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
151	tefluthrin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
152	terbacil	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
153	terbufos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
154	tetrachlorvinphos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
155	tetraconazole	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
156	tetradifon	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
157	tetramethrin	With reference to US FDA PAM, GB/T 19648-2006	0.02	N
158	thiometon	With reference to US FDA PAM, GB/T 19648-2006	0.05	N
159	Tolclofos-methyl	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
160	tolylfluanid	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
161	tralomethrin	With reference to US FDA PAM, GB/T 19648-2006	0.1	N
162	triadimefon	With reference to US FDA PAM, GB/T 19648-2006	0.02	N
163	triallate	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
164	triazophos	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
165	trifluralin	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
166	vinclozoline	With reference to US FDA PAM, GB/T 19648-2006	0.01	N
167	3,4,5-trimethacarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N

TJFD 007312

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Test Report **No: TJFDO110400701FD** **Date: May 16 2011**

Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
168	6-chloro-4-hydroxy-3-phenyl-pyridazin	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
169	Acephate	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
170	Acetamiprid	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
171	Acetochlor	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
172	Aldicarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
173	Aldicarb-sulfoxid	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
174	Aldoxycarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
175	Amidosulfuron	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
176	Atrazine	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
177	Azaconazole	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
178	Azinphos-methyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
179	Azoxystrobin (Pyroxystrobin)	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
180	Bendiocarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
181	Benoxacor	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
182	Bensulfuron-methyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
183	Bifenox	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
184	Bupirimate	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
185	Buprofezin	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
186	Butafenacil	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
187	Butocarboxim	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
188	Butoxycarboxim	With reference to US FDA PAM, GB/T 20769-2008	0.01	N

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Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
210	Fenhexamid	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
211	Fenobucarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
212	Fenoxaprop-ethyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
213	Fenoxycarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
214	Fenpropimorph	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
215	Fenpyroximate	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
216	Flamprop-methyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
217	Flazasulfuron	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
218	Fluazifop-p-butyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
219	Flufenoxuron	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
220	Flumiclorac pentyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
221	Furathiocarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
222	Haloxyfop-ethoxyethyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
223	Haloxyfop-methyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
224	Hexythiazox	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
225	Imazalil	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
226	Imidacloprid	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
227	Indoxacarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
228	Iprobenfos	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
229	Iprovalicarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
230	Isoprocarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N

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TJFD 007309

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Test Report **No: TJFDQ110400701FD** **Date: May 16 2011**

Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
231	Isoprothiolane	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
232	Isoproturon	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
233	Isoxaflutole	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
234	Kresoxim-methyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
235	Lactofen	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
236	Linuron	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
237	Malathion	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
238	Metalaxyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
239	Metamitron	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
240	Methamidophos	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
241	Methidathion	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
242	Methiocarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
243	Methomyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
244	Metolachlor	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
245	Metsulfuron-methyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
246	Mevinphos	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
247	Molinate	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
248	Monocrotophos	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
249	Nicosulfuron	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
250	Omethoate	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
251	Oxadiazon	With reference to US FDA PAM, GB/T 20769-2008	0.01	N

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Test Report **No: TJFDO110400701FD** **Date: May 16 2011**

Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
252	Oxadixyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
253	Oxamyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
254	Oxydemeton-methyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
255	Oxyfluorfen	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
256	Pencycuron	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
257	Phosalone	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
258	Phosmet	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
259	Phoxim	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
260	Pirimicarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
261	Pretilachlor	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
262	Prochloraz	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
263	Promecarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
264	Propachlor	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
265	Propamocarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
266	Propargite	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
267	Propoxur	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
268	Prosulfuron	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
269	Pymetrozine	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
270	Pyraflufen-ethyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
271	Pyrazoxyfen	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
272	Pyridaben	With reference to US FDA PAM, GB/T 20769-2008	0.01	N

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Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
273	Pyridaphenthion	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
274	Pyrimethanil	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
275	Quinoxyfen	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
276	Quizalofop-ethyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
277	Rimsulfuron	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
278	Simazine	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
279	Simetryn	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
280	Spiroxamine	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
281	Tebuconazole	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
282	Tebufenozide	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
283	Tebufenpyrad	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
284	Terbutryne	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
285	Thenylchlor	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
286	Thiabendazole	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
287	Thiacloprid	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
288	Thiamethoxam	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
289	Thiazopyr	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
290	Thifensulfuron-methyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
291	Thiobencarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
292	Thiodicarb	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
293	Thiofanox-sulfon	With reference to US FDA PAM, GB/T 20769-2008	0.01	N

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Test Report **No: TJFDO110400701FD** **Date: May 16 2011**

Code	Test Item(s)	Test Method(s)	Method Detection Limit(s) mg/kg	Test Result(s) mg/kg
294	Thiofanox-sulfoxid	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
295	Thiophanate methyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
296	Triadimenol	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
297	Triasulfuron	With reference to US FDA PAM, GB/T 20769-2008	0.01	NR
298	Trichlorphon	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
299	Trifloxystrobin	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
300	Triflumizole	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
301	Triflusulfuron-methyl	With reference to US FDA PAM, GB/T 20769-2008	0.01	N
302	Vamidothion	With reference to US FDA PAM, GB/T 20769-2008	0.01	N

Notes :

Trace: Has signal(Response Factor < MDL)
N: Negative(No Response)
NR: Not recoveried.

*** End of Report***

TJFD 007305

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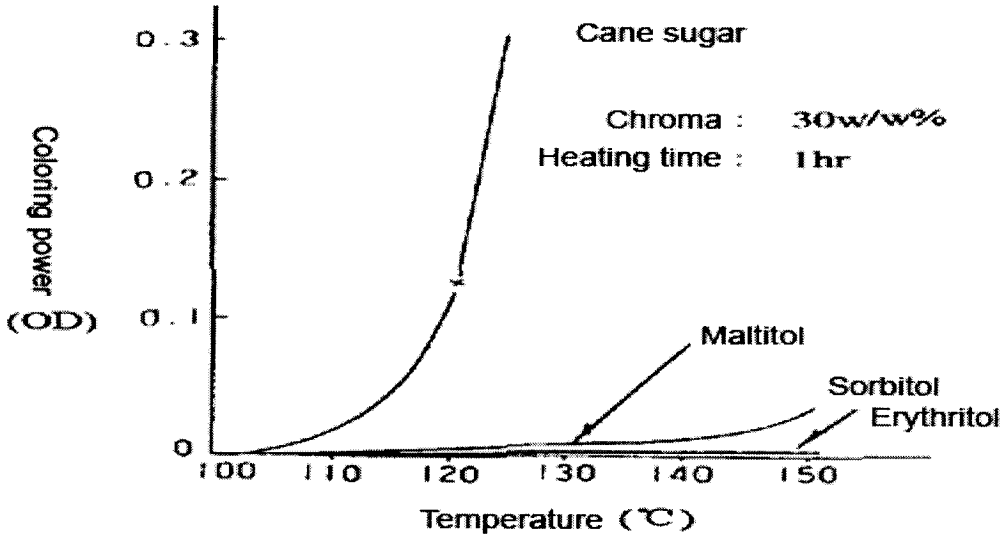
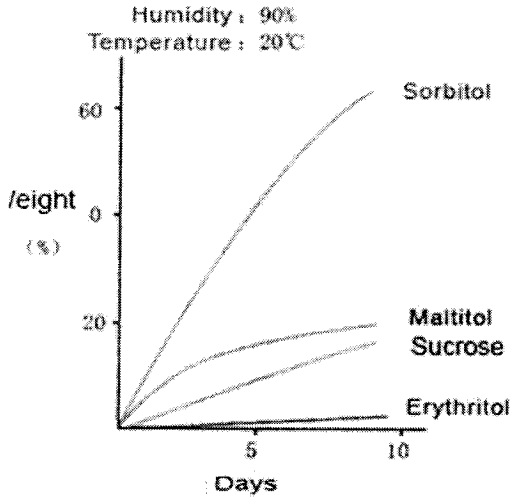
APPENDIX G

Stability Data on O'Laughlin's Erythritol

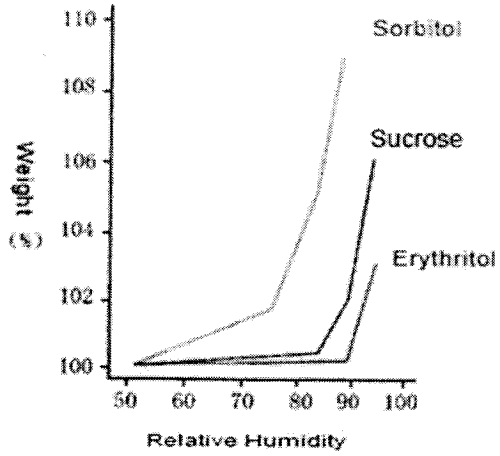
Acid Thermal Stability of Erythritol



Erythritol Moisture Situation with Other Sweeteners。



a. Under humidity 90%, the change in weight as time goes on.



b. The moisture absorption of sweeteners under different humidity

Submission End

SUBMISSION END